

Comparative Effectiveness of In-Hospital Use of Recombinant Factor VIIa for Off-Label Indications vs. Usual Care

Appendixes

Appendix A. Search Strategies

OID MEDLINE

1948 to August 4, 2009

Search 1: Factor VIIa Off-Label Use

Rather than trying to represent “off-label” use with MeSH terms or keywords, this search included any article on Factor VIIa *except* case reports, editorials, animal-only studies and non-systematic reviews. This search does include systematic reviews.

1. exp factor viia/ OR ("factor viia" OR "factor 7a" OR rfvia OR fvia) OR (novoseven OR eptacog* OR Niastase OR proconvertin OR "novo-seven") OR ec 3 4 21 21.rn. OR ((7a or viia) adj5 (factor OR rfactor)) OR (("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated))

2. case reports OR editorial OR "review"

3. animals/ not humans/

1 NOT (2 OR 3 OR “ALL RESULTS FROM THE NEXT THREE SEARCHES”)

Number of citations: 1684

Search 2: Intracranial Hemorrhages AND Factor VIIa

1. exp factor viia/ OR ("factor viia" OR "factor 7a" OR rfvia OR fvia) OR (novoseven OR eptacog* OR Niastase OR proconvertin OR "novo-seven") OR ec 3 4 21 21.rn. OR ((7a or viia) adj5 (factor OR rfactor)) OR (("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated))

2. exp Intracranial Hemorrhages/ OR exp brain/ OR exp skull/ OR intracranial.mp. OR intracerebral.mp. OR "basal ganglia".mp. OR brain*.mp. OR "posterior fossa".mp. OR cerebral.mp. OR parenchymal.mp. OR subdural.mp. OR subarachnoid.mp. OR pituitary.mp. OR epidural.mp

3. animals/ not humans/

(1 AND 2) NOT 3

Number of citations: 293

Search 3: Trauma AND Factor VIIa

1. exp factor viia/ OR ("factor viia" or "factor 7a" OR rfviia OR fviia) OR (novoseven or eptacog* OR Niastase OR proconvertin OR "novo-seven") OR ec 3 4 21 21.rn. OR ((7a or viia) adj5 (factor OR rfactor)) OR (("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated))

2. exp "Wounds and Injuries"/ OR (traum* or injur* or wound*).mp.

3. animals/ not humans/

(1 AND 2) NOT 3

Number of citations: 459

Search 4: Liver Transplantation/Cardiac Surgery/Prostatectomy AND Factor VIIa

1. exp factor viia/ OR ("factor viia" or "factor 7a" OR rfviia OR fviia) OR (novoseven or eptacog* OR Niastase OR proconvertin OR "novo-seven") OR ec 3 4 21 21.rn. OR ((7a or viia) adj5 (factor OR rfactor)) OR (("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated))

2. exp liver transplantation/ OR ((liver* or hepatic) adj3 (transplan* or graft*).mp. OR exp Cardiovascular Diseases/su [Surgery] OR exp cardiovascular surgical procedures/ OR ((heart* or cardi*) and surg*).mp. OR exp Prostatectomy/ OR (Prostatectom* or (resect* and prostat*).mp.

3. animals/ not humans/

(1 AND 2) NOT 3

Number of citations: 294

Total number of citations from OVID/MEDLINE search: 3067

EMBASE (DIALOG) 1974 to August 4, 2009

Search 1: FACTOR VIIa NOT Letters, NOT Animal-only Studies

S1 FACTOR VIIA! OR FACTOR()VIIA OR FACTOR()7A OR RFVIIA
OR FVIIA OR NOVOSEVEN OR EPTACOG? OR NIASTASE OR PROCONV-
ERTIN OR NOVO()SEVEN

S2 (7A OR VIIA)(5N)(FACTOR OR RFACTOR)

S3 (FACTOR()VII OR FACTOR()7 OR FVII OR RFVII OR FACTOR-
(SEVEN)(5N)(ACTIVE OR ACTIVATED)

S4 DT=LETTER

S5 (ANIMALS/DE OR NONHUMANS/DE) NOT (HUMANS/DE OR HUMAN-
/DE)

S6 S1 OR S2 OR S3

S7 S6 NOT (S4 OR S5)

**Search 2: FACTOR VIIa AND Intracranial Hemorrhage NOT Animal-only
Studies**

S9 BRAIN! OR SKULL! OR INTRACRANIAL OR INTRACEREBRAL OR
BASAL()GANGLIA OR BRAIN? OR POSTERIOR()FOSSA OR CEREBRAL
OR PARENCHYMAL OR SUBDURAL OR SUBARACHNOID OR PITUITARY -
OR EPIDURAL

S10 BRAIN HEMORRHAGE! OR INTRACRANIAL HEMORRHAGES!

S11 (STROKE! OR CVA OR STROKE OR APOPLEXY OR BRAIN()VASC-
ULAR()ACCIDENT? OR CEREBROVASCULAR()ACCIDENT OR CEREBROV-
ASCULAR ACCIDENT/DE) AND (HEMORRHAGE! OR BLEEDING! OR H-
EMORRHAG? OR BLEED?)

S12 S6 NOT S5

S13 s12 AND (S24 OR S13 OR S18)

Search 3: FACTOR VIIa and Liver Transplantation/Heart Surgery/Prostatectomy NOT Animal-
only Studies

S15 LIVER TRANSPLANTATION!

S16 (LIVER? OR HEPATIC)(5N)(TRANSPLANT? OR GRAFT?)

S17 CARDIOVASCULAR SURGICAL PROCEDURES! OR CARDIOVASCULAR
SURGERY!

S18 CARDIOVASCULAR DISEASES!

S19 S32(L)SU

S20 CARDIOVASCULAR DISEASE!

S21 S20(L)SU

S22 (HEART? OR CARDI?) AND (SURG? OR PRESURG? OR POSTSURG? OR PERIOPERAT? OR OPERATION? OR OPERATIVE OR PERIOPERAT? OR PREOPERAT? OR POSTOPERAT? OR RESECT?)/TI,AB,DE

S23 PROSTATECTOMY!

S24 PROSTATECTOM? OR ((SURG? OR PRESURG? OR POSTSURG? OR PERIOPERAT? OR OPERATION? OR OPERATIVE OR PERIOPERAT? OR PREOPERAT? OR POSTOPERAT? OR RESECT?) AND PROSTAT?)

S25 (S15-S24 combined with OR) AND S12

Search 4: FACTOR VIIa and Trauma NOT Animal-only Studies

S27 DC='C21.866.' (WOUNDS AND INJURIES)

S28 TRAUM? OR INJUR? OR WOUND?

S29 S12 AND (S27 OR S28)

Total number of citations from EMBASE search: 4424

All OVID EBM Review Databases (Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED) No date restrictions. Searched up to August 4, 2009

Factor VIIa Off-Label Use

"factor viia" or "factor 7a" OR rfvia OR fvia OR novoseven or eptacog* OR Niastase OR proconvertin OR "novo-seven" OR (7a or viia) adj5 (factor OR rfactor) OR ("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated)

Number of citations: 161

BIOSIS (ISI) 1926 to August 4, 2009

Factor VIIa Off-Label Use

Broad search aimed at retrieving all articles on Factor VIIa, but excluding letters and animal-only studies.

"factor viia" or "factor 7a" OR rfvia OR fvia OR novoseven or eptacog* OR Niastase OR proconvertin OR "novo-seven" OR (7a or viia) adj5 (factor OR rfactor) OR ("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated)

1 NOT Letters

2 NOT animals NOT humans

Number of citations: 3190

Total number of unique citations from all databases (after removing duplicate citations): 5668

Appendix B. List of Excluded Studies

Excluded article	Reason for exclusion
Abdullah F, Hunter C, Hargrove C, et al. Recombinant factor VIIa for treatment of massive liver fracture in a premature infant. <i>J Pediatr Surg</i> 2006;41(10):1764-1767.	Ineligible study design
Abraldes JG, Dell'Era A, Bosch J. Medical management of variceal bleeding in patients with cirrhosis. <i>Can J Gastroenterol</i> 2004;18(2):109-113.	Ineligible study design
Abu-Hajir M, Hollowell J, Nagargoje G. Management of 2 patients with subdural hematoma and coagulopathy with recombinant human activated Factor VII (novoseven, rVIIa). <i>Blood</i> . 2001;98(11 Part 2):79b.	Small sample size
Adams GL, Manson RJ, Turner I, et al. The balance of thrombosis and hemorrhage in surgery. <i>Hematol Oncol Clin North Am</i> 2007;21(1):13-24.	Ineligible study design
Afessa B, Peters SG. Major complications following hematopoietic stem cell transplantation. <i>Semin Respir Crit Care Med</i> 2006;27(3):297-309.	Ineligible study design
Agarwal MB, Patnaik M. Recombinant activated factor VII (rFVIIa, NovoSeven). <i>Journal of the Association of Physicians of India</i> 2005;53:717-720.	Ineligible study design
Agarwal N, Spahr JE, Rodgers GM. Successful management of intra-abdominal hemorrhage in the presence of severe alcoholic liver disease with activated recombinant factor VII (rFVIIa; NovoSeven): a case report and review of the literature on approved and off-label of rFVIIa. <i>Blood Coagulation & Fibrinolysis</i> 2007;18(2):205-207.	Ineligible study design
Aggarwal A, Catlett J, Alcorn K. Use of recombinant activated factor VII (rFVIIa) in the management of intractable bleeding in surgical and trauma patients. <i>Blood</i> . 2001;98(11 Part 2):66b.	Small sample size
Aguilar C, Lucia JF. Successful control of severe postoperative bleeding with recombinant factor VIIa in a case of refractory idiopathic thrombocytopenic purpura. <i>Am J Hematol</i> 2007;82(3):246-247.	Ineligible study design
Aguilar MI, Dernaerschalk BM. Intracerebral Hemorrhage. <i>Seminars in Neurology</i> . 2007;27(4):376-384.	Ineligible study design
Aguilar MI, Hart RG, Kase CS, et al. Treatment of warfarin-associated intracerebral hemorrhage: literature review and expert opinion.[erratum appears in <i>Mayo Clin Proc</i> 2007 Mar;82(3):387]. <i>Mayo Clinic Proceedings</i> 2007;82(1):82-92.	Ineligible study design
Ahonen J, Jokela R. Recombinant factor VIIa for life-threatening post-partum haemorrhage[see comment]. <i>British Journal of Anaesthesia</i> 2005;94(5):592-595.	Ineligible study design
Aitken MG. Recombinant factor VIIa. <i>Emerg Med Australas</i> 2004;16(5-6):446-455.	Ineligible study design
Aiyagari V, Diringner MN. Response to discussion by Dr Philip Hebert. Use of recombinant activated factor VIIa (FVIIa) in severe head injury. <i>J Crit Care</i> 2006;21(1):115-116; author reply 116.	Ineligible study design
Aiyagari V, Menendez JA, Diringner MN. Treatment of severe coagulopathy after gunshot injury to the head using recombinant activated factor VII. <i>J Crit Care</i> 2005;20(2):176-179.	Small sample size
Akyildiz M, Turan I, Ozutemiz O, et al. A cerebrovascular event after single-dose administration of recombinant factor VIIa in a patient with esophageal variceal bleeding. <i>Digestive Diseases & Sciences</i> 2006;51(9):1647-1649.	Ineligible study design
Al Douri M, Shafi T, Al Khudairi D, et al. Effect of the administration of recombinant activated factor VII (rFVIIa; NovoSeven) in the management of severe uncontrolled bleeding in patients undergoing heart valve replacement surgery. <i>Blood Coagul Fibrinolysis</i> 2000;11 Suppl 1:S121-S127.	Small sample size
Al Hammadi AM, Sallah S. Efficacy and safety of recombinant factor VIIa in the treatment of bleeding episodes in patients with aplastic anemia. <i>Journal of Thrombosis & Haemostasis</i> 2007;5(2):435-436.	Ineligible study design
Al Sobhi E, Zahrani Z, Zevallos E, et al. Imatinib-induced immune hepatitis: case report and literature review. <i>Hematology</i> 2007;12(1):49-53.	Ineligible study design
Al Sobhi E. Successful outcome of using recombinant activated factor VII (rFVIIa) in liver biopsy in a patient with liver failure. <i>J Thromb Haemost</i> 2006;4(9):2073-2074.	Ineligible study design
Alameri A, Baker NS. Successful use of recombinant activated factor VII in the treatment of vitreous haemorrhage: a report of seven cases. <i>Blood Coagulation & Fibrinolysis</i> 2005;16(8):573-578.	Small sample size
Alavi AA, Jalali SM, Rasouli MR, et al. Administration of recombinant activated factor VII in major thoracic operations comment]. <i>Archives of Surgery</i> 2008;143(10):1021; author reply 1021.	Other: unpublished data

Excluded article	Reason for exclusion
Alcorn K, Aggarwal A. Single Institution Experience of Recombinant Activated Factor VII (Novo-Seven) in the Management of Intractable Bleeding in Surgical and Trauma Patients. <i>Blood</i> 2002;100(11):Abstract No. 3840.	Data combined for multiple conditions
Aldouri M. The use of recombinant factor VIIa in controlling surgical bleeding in non-haemophiliac patients. <i>Pathophysiology of Haemostasis & Thrombosis</i> 2002;32 Suppl 1:41-46.	Small sample size
Aledort LM. Activated prothrombin complex concentrates and recombinant factor VIIa in the bleeding patient: are they appropriate and safe? [comment]. <i>Journal of Thoracic & Cardiovascular Surgery</i> 2003;126(6):2112-2113.	Ineligible study design
Aledort LM. Adverse reactions related to rVIIa? <i>Am J Hematol</i> 2001;67(3):213.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Aledort LM. Comparative thrombotic event incidence after infusion of recombinant factor VIIa versus factor VIII inhibitor bypass activity.[see comment]. <i>Journal of Thrombosis & Haemostasis</i> 2004;2(10):1700-1708.	Ineligible study design
Aledort LM. MedWatch: an important instrument for postlicensing surveillance.[comment]. <i>Journal of Thrombosis & Haemostasis</i> . 2006;4(7):1637.	Ineligible study design
Aledort LM. Recombinant factor VIIa is a pan-hemostatic agent? <i>Thromb Haemost</i> 2000;83(5):637-638.	Other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)
Aledort LM. rFVIIa--its thrombogenicity. <i>Thromb Haemost</i> 2000;84(3):522-523.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Alexander E. Emerging role of recombinant factor VIIa in neuroscience. <i>AACN Adv Crit Care</i> 2006;17(4):363-367.	Ineligible study design
Alfirevic Z, Elbourne D, Pavord S, et al. Use of recombinant activated factor VII in primary postpartum hemorrhage - The northern European registry 2000-2004. <i>Obstetrics & Gynecology</i> 2007;110(6):1270-1278.	Ineligible study design
Alfirevic Z, Elbourne D, Pavord S, et al. Use of recombinant activated factor VII in primary postpartum hemorrhage: the Northern European registry 2000-2004. <i>Obstet Gynecol</i> 2007;110(6):1270-1278.	Ineligible study design
Ali ZS, Al-Shaalan H, Jorgensen J. Successful treatment of massive acute lower gastrointestinal bleeding in diverticular disease of colon, with activated recombinant factor VII (NovoSeven). <i>Blood Coagul Fibrinolysis</i> 2006;17(4):327-329.	Ineligible study design
Alimoghaddam K, Ghavamzadeh A, Jahani M. Use of Novoseven for arsenic trioxide-induced bleeding in PML. <i>American Journal of Hematology</i> 2006;81(9):720.	Ineligible study design
Al-Khuwaitir TS, Al-Moghairi AM, Sherbeeni SM, et al. Rift Valley fever hepatitis complicated by disseminated intravascular coagulation and hepatorenal syndrome. <i>Saudi Med J</i> 2004;25(4):528-531.	Ineligible study design
Allard S, Earley J, Davies JK, et al. Hospital blood transfusion services in a mass casualty situation: lessons to be learned from July 2005 London bombings. <i>British Journal of Haematology</i> 2006;133(Suppl. 1):2.	Ineligible study design
Allen GA, Hoffman M, Roberts HR, et al. Recombinant activated factor VII: its mechanism of action and role in the control of hemorrhage. <i>Canadian Journal of Anaesthesia</i> 2002;49(10):S7-S14.	Ineligible study design
Allen KB, Heimansohn DA. Activated recombinant factor VII: Safety assessment in cardiovascular surgery patients at high risk for postoperative bleeding. <i>Chest</i> 2006;130(4, Suppl S):187S.	Small sample size
Al-Ruzzeh S, Mahmoud A, Shah S, et al. Caution with the use of recombinant activated factor VII in treating postoperative hemorrhage in cardiac surgery. <i>Ann Thorac Surg</i> 2007;83(1):355; author reply 355-356.	Ineligible study design
Al-Said K, Anderson R, Wong A, et al. Recombinant factor VIIa for intraoperative bleeding in a child with hepatoblastoma and review of recombinant activated factor VIIa use in children undergoing surgery. <i>Journal of Pediatric Surgery</i> 2008;43(4):e15-e19.	Ineligible study design

Excluded article	Reason for exclusion
Alsayegh F, Fakeir A, Alhumood S, et al. Use of recombinant activated factor VII to arrest uncontrolled bleeding: a case series. <i>Clinical & Applied Thrombosis/Hemostasis</i> 2009;15(2):225-232	Small sample size
Al-Shahi R, You H. Hemostatic Drug Therapies for Acute, Nontraumatic Intracerebral Hemorrhage. <i>Stroke</i> 2006.	Ineligible study design
Al-Trabolsi H, Carcao MD, Freedman J, et al. Factor VIIa overdose: Clinical and laboratory observations. <i>Blood</i> 1998;92(10 Suppl 1 Part 1-2):104B.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Altuncu E, Berrak S, Bilgen H, et al. Use of recombinant factor VIIa in a preterm infant with coagulopathy and subdural hematoma. <i>Journal of Maternal-Fetal & Neonatal Medicine</i> 2007;20(8):627-629.	Small sample size
Alving BM. Platelet substitutes: The reality and the potential. <i>Vox Sanguinis</i> 2002;83(Suppl 1):287-288.	Ineligible study design
Anantharaju A, Mehta K, Mindikoglu AL, et al. Use of activated recombinant human factor VII (rhFVIIa) for colonic polypectomies in patients with cirrhosis and coagulopathy. <i>Digestive Diseases and Sciences</i> 2003;48(7):1414-1424.	Ineligible study design
Anderson JAM, Cook MK, Ludlam CA. Can factor VIIa alone secure haemostasis in patients with liver cirrhosis? <i>Haemostasis</i> 2000;30(Suppl 1):197-198.	Ineligible study design
Andonova R, Gavrilova N, Bogdanova R, et al. Initial experience with recombinant activated factor VII (NovoSeven(R)) in trauma and surgery paediatric cases of uncontrolled bleeding. <i>Anaesthesiology and Intensive Care</i> 2006;33(2):7-12.	Unable to obtain publication
Andrews TR, Dwyer JP, Rivera CE. Use of NovoSeven (Recombinant human coagulation factor VIIa) as treatment for bleeding in multiple myeloma with a factor VII clearing antibody. <i>Blood</i> 2003;102(11):108b.	Ineligible study design
Anonymous. 21st Annual Meeting of the European-Association-of-Cardiothoracic-Anaesthesiologists, Venice, Italy, May 24-27, 2006. <i>European Journal of Anaesthesiology</i> 2006;23(Suppl 38):1-47.	Other: conference proceedings
Anonymous. 40th Annual Meeting of the German-Society-for-Transfusion-Medicine-and-Immunohematology, Friedrichshafen, Germany, September 18-21, 2007. <i>Transfusion Medicine and Hemotherapy</i> 2007;34(Suppl 1):1-74.	Other: conference proceedings
Anonymous. Annual Scientific Meeting of the Trauma-Association-of-Canada, Whistler, Canada, April 03-05, 2008. <i>Journal of Trauma Injury Infection and Critical Care</i> 2008;64(2):544-559.	Duplicate
Anonymous. Controlled off-label use of recombinant activated factor VII (NovoSeven) can build evidence base. <i>Cardiovascular Journal of Africa</i> 2008;19(1):52-54.	Ineligible study design
Anonymous. Meeting on Haemostasis and Transfusion: Perioperative Management in Elderly Patients, Graz, Austria, October 27-28, 2000. <i>Infusion Therapy and Transfusion Medicine</i> 2001;28(2):97-118.	Duplicate
Anonymous. Proceedings of the 4th Symposium on Hemostasis with Special Focus on Factor VIIa and Tissue Factor-Understanding the Molecular Mechanism. April 3-5, 2008. Chapel Hill, North Carolina. <i>Thrombosis Research</i> 2008;122 Suppl 1:S1-S81.	Animal or in-vitro study
Anonymous. Proceedings of the 9th Novo Nordisk Symposium on Haemostasis Management, November 15-16, 2007, Barcelona, Spain. <i>Seminars in Hematology</i> 2008;45(2 Suppl 1):S1-S74.	Ineligible study design
Ansari S, Salehi S. Coagulopathy after spider bites to a 6-year-old boy. <i>Pediatr Hematol Oncol</i> 2007;24(3):233-523.	Ineligible study design
Ansell J, Hirsh J, Hylek E, et al. Pharmacology and management of the vitamin K antagonists. <i>Chest</i> 2008;133(6 Suppl S):160S-198S.	Ineligible study design
Apostolidou I, Sweeney MF, Missov E, et al. Acute left atrial thrombus after recombinant factor VIIa administration during left ventricular assist device implantation in a patient with heparin-induced thrombocytopenia. <i>Anesth Analg</i> 2008;106(2):404-408, table of contents.	Small sample size
Arai M. Factor VIIa in acute intracerebral haemorrhage. <i>ClinicalTrials.gov</i> . 2005.	No usable data
Argall J, Teece S, Mackway-Jones K. Factor VIIa for intractable blood loss in trauma. <i>Emerg Med J</i> 2002;19:556-557.	Ineligible study design
Argall J, Teece S. Towards evidence based emergency medicine: best BETs from Manchester Royal Infirmary. Factor VIIa for intractable blood loss in trauma. <i>Emerg Med J</i> 2002;19(6):556-557.	Ineligible study design

Excluded article	Reason for exclusion
Arthurs Z, Cuadrado D, Beekley A, et al. The impact of hypothermia on trauma care at the 31st combat support hospital. <i>American Journal of Surgery</i> 2006;191(5):610-614.	No usable data
Ashrani AA, Gabriel DA, Gajewski JL, et al. Pilot study to test the efficacy and safety of activated recombinant factor VII (NovoSeven) in the treatment of refractory hemorrhagic cystitis following high-dose chemotherapy. <i>Bone Marrow Transplantation</i> 2006;38(12):825-828.	Ineligible study design
Ashrani AA, Gabriel DA, Gajewski JL, et al. Pilot study to test the efficacy and safety of recombinant factor VIIa (rFVIIa, NovoSeven (TM)) in the treatment of refractory hemorrhagic cystitis following high dose chemotherapy. <i>Blood</i> 2004;104(11 Part 1):322A.	Ineligible study design
Athale UH, Chan AK. Hemorrhagic complications in pediatric hematologic malignancies. <i>Semin Thromb Hemost</i> 2007;33(4):408-415.	Ineligible study design
Atkison PR, Jardine L, Williams S, et al. Use of recombinant factor VIIa in pediatric patients with liver failure and severe coagulopathy. <i>Transplant Proc</i> 2005;37(2):1091-1093.	Ineligible study design
Auer RN, Sutherland GR. Primary intracerebral hemorrhage: pathophysiology. <i>Canadian Journal of Neurological Sciences</i> . 2005;32 Suppl 2:S3-S12.	Ineligible study design
Auriel E, Bornstein NM. Treatment of acute intracerebral hemorrhage. <i>Israel Medical Association Journal: Imaj</i> 2006;8(11):812-814.	Ineligible study design
Bacigalupo A. Haemopoietic stem cell transplants: The impact of haemorrhagic complications. <i>Blood Reviews</i> 2003;17(Suppl 1):S6-S10.	Ineligible study design
Badjatia N, Rosand J. Intracerebral hemorrhage. <i>Neurologist</i> 2005;11(6):311-324.	Ineligible study design
Badra G, El-Abassy M, Loffy M, et al. A life-sustaining single dose of recombinant activated factor VII for an Egyptian patient with hemorrhagic crisis. <i>Saudi Med J</i> 2007;28(6):979-981.	Ineligible study design
Baker DS, Shenoy S. Treatment of non-hemophilic disorders in children with recombinant FVIIa - A review of dosing, safety, and efficacy. <i>Blood</i> 2005;106(11 Part 2):122B.	Ineligible study design
Baldi G, Altomonte F, Altomonte M, et al. Intracranial haemorrhage in patients on antithrombotics: clinical presentation and determinants of outcome in a prospective multicentric study in Italian emergency departments. <i>Cerebrovasc Dis</i> 2006;22(4):286-293.	Small sample size
Balen S, Roganovic I, Vukelic-Damiani N. Recombinant factor VIIa in treatment of severe thrombocytopenic patients: case report. <i>Vox Sanguinis</i> 2005;89(Suppl 1):195.	Ineligible study design
Ballen J, Raabe M, Muirhead B. Aortic dissection and hypothermic arrest in a Jehovah's Witness patient: a case for recombinant factor VIIa? [see comment]. <i>Canadian Journal of Anaesthesia</i> 2006;53(4):353-356.	Small sample size
Barbui T, Caruso V, Tognoni G, et al. Prognosis of veno-occlusive disease after stem cell transplantation in the DF-VOD trial. On behalf of the DF-VOD investigators. <i>Blood</i> 2004;104(11 Part 1):322A.	Not on rFVIIa
Barcelona SL, Thompson AA, Cote CJ. Intraoperative pediatric blood transfusion therapy: a review of common issues. Part II: transfusion therapy, special considerations, and reduction of allogenic blood transfusions. <i>Paediatric Anaesthesia</i> 2005;15(10):814-830.	Ineligible study design
Barkagan ZS. Pathogenesis and therapy of hemostatic disorders in cancer patients. <i>Terapevticheskii Arkhiv</i> 1997;69(7):65-67.	Ineligible study design
Barkagan ZS. The role of hemostasis system components in therapy of DIC-syndrome and thrombophilias. <i>Gematologiya i Transfuziologiya</i> 2005;50(6):9-12.	Ineligible study design
Barnes C, Blanchette V, Canning P, et al. Recombinant FVIIa in the management of intracerebral haemorrhage in severe thrombocytopenia unresponsive to platelet-enhancing treatment. <i>Transfusion Medicine</i> 2005;15(2):145-150.	Small sample size
Barro C, Wroblewski I, Piolat C, et al. Successful use of recombinant factor VIIa for severe surgical liver bleeding in a 5 month-old baby. <i>Haemophilia</i> 2004;10(2):183-185.	Ineligible study design
Basile VS, Silver FL. Recombinant activated factor VII given within 4 hours of intracerebral hemorrhage reduced hematoma growth [comment]. <i>ACP Journal Club</i> 2005;143(2):34.	Duplicate
Baudo F, Caimi TM, Mostarda G, et al. Critical bleeding in pregnancy: a novel therapeutic approach to bleeding. <i>Minerva Anestesiologica</i> 2006;72(6):389-393.	Ineligible study design
Bauza G, Hirsch E, Burke P, et al. Low-dose recombinant activated factor VII in massively transfused trauma patients with coagulopathy. <i>Transfusion</i> 2007;47(4):749-751.	Small sample size

Excluded article	Reason for exclusion
Baxter MS, Schroeder WS, Cheng Y, et al. Diminished response to recombinant factor VIIa in a patient with idiopathic thrombocytopenic purpura. <i>Annals of Pharmacotherapy</i> 2006;40(11):2053-2058.	Ineligible study design
Becton D, Saylor R, Morris J, et al. Treatment of bleeding with rFVIIa (NovoSeven(R)) in four diverse cases. <i>Blood</i> 2001;98(11 Part 1):263a.	Small sample size
Beldowicz BC, McDonald JM, Needham CS. Confirmed graft flow following use of recombinant factor VIIa in coronary artery bypass grafting: a case report and literature review. <i>Journal of Cardiac Surgery</i> 2006;21(5):483-486.	Small sample size
Bendtsen F, Krag A, Moller S. Treatment of acute variceal bleeding. <i>Dig Liver Dis</i> 2008;40(5):328-336.	Ineligible study design
Benharash P, Bongard F, Putnam B. Use of recombinant factor VIIa for adjunctive hemorrhage control in trauma and surgical patients. <i>American Surgeon</i> 2005;71(9):776-780.	Small sample size
Ben-Tal O, Misgav M, Kluger Y, et al. Recombinant activated factor VII (NovoSevenTM), an adjunct to replacement therapy in acute, uncontrolled, life threatening bleeding. <i>Blood</i> 2003;102(11):132b.	Ineligible study design
Berkhof FF, Eikenboom JC, Berkhof FF, et al. Efficacy of recombinant activated Factor VII in patients with massive uncontrolled bleeding: a retrospective observational analysis. <i>Transfusion</i> 2009;49(3):570-577.	Small sample size
Bernstein D. Effectiveness of the recombinant factor VIIa in patients with the coagulopathy of advanced child's B and C cirrhosis. <i>Seminars in Thrombosis and Hemostasis</i> 2000;26(4):437-438.	Ineligible study design
Bernstein DE, Glazer S, Jeffers LJ, et al. Recombinant VIIa (rFVIIa) in the treatment of prolonged prothrombin times (PT) in cirrhotics. <i>Hepatology</i> 1995;22(4 part 2):289A.	Ineligible study design
Bernstein DE, Jeffers L, Erhardtsen E, et al. Recombinant factor VIIa corrects prothrombin time in cirrhotic patients: a preliminary study. <i>Gastroenterology</i> 1997;113(6):1930-1937.	Ineligible study design
Berntorp E, Stigendal L, Lethagen S, et al. NovoSeven in warfarin-treated patients. <i>Blood Coagul Fibrinolysis</i> 2000;11 Suppl 1:S113-S115.	Ineligible study design
Berntorp E. Recombinant FVIIa in the treatment of warfarin bleeding. <i>Seminars in Thrombosis and Hemostasis</i> 2000;26(4):433-435.	Ineligible study design
Berthier AM, Guillygomarc'h A, Messner M, et al. Use of recombinant factor VIIa to treat persistent bleeding following dental extractions in two cirrhotic patients. <i>Vox Sang</i> 2002;82(3):119-121.	Ineligible study design
Betensley AD, Yankaskas JR. Factor viia for alveolar hemorrhage in microscopic polyangiitis. <i>Am J Respir Crit Care Med</i> 2002;166(9):1291-1292.	Ineligible study design
Bhalla A, Hargroves D. Does early medical intervention have a role in the management of intracerebral haemorrhage? <i>Int J Clin Pract</i> 2008;62(4):633-641.	Ineligible study design
Bhullar IS, Braman R, Block EF. Recombinant factor VII as an adjunct to control of hemorrhage from chest trauma in a Jehovah's Witness. <i>Am Surg</i> 2007;73(8):818-819.	Small sample size
Bhuskute N, Kritzinger S, Dakin M. Recombinant factor VIIa in massive obstetric haemorrhage. <i>Eur J Anaesthesiol</i> 2008;25(3):250-251.	Ineligible study design
Bianchi A, Jackson D, Maitz P, et al. Treatment of bleeding with recombinant factor VIIa in a patient with extensive burns. <i>Thromb Haemost</i> 2004;91(1):203-204.	Ineligible study design
Biancofiore G, Bisa M, Bindi LM, et al. Liver transplantation due to Herpes Simplex virus-related sepsis causing massive hepatic necrosis after thoracoscopic thymectomy. <i>Minerva Anesthesiol</i> 2007;73(5):319-322.	Small sample size
Bijsterveld NR, Moons AH, Boekholdt SM, et al. Ability of recombinant factor VIIa to reverse the anticoagulant effect of the pentasaccharide fondaparinux in healthy volunteers. <i>Circulation</i> 2002;106(20):2550-2554.	In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
Billio A, Morello E, Amaddii G, et al. Treatment of Refractory Thrombocytopenic Bleeding with rFVII: A Case Report. <i>Blood</i> 2002;100(11):Abstract No. 3806.	Ineligible study design
Birchall J, Stanworth SJ, Duffy MR, et al. Evidence for the use of recombinant factor VIIa in the prevention and treatment of bleeding in patients without hemophilia. <i>Transfusion Medicine Reviews</i> 2008;22(3):177-187.	Ineligible study design
Bishop CV, Renwick WE, Hogan C, et al. Recombinant activated factor VII: treating postoperative hemorrhage in cardiac surgery. <i>Ann Thorac Surg</i> 2006;81(3):875-879.	Small sample size
Biss TT, Hanley JP. Recombinant activated factor VII (rFVIIa/NovoSeven) in intractable haemorrhage: use of a clinical scoring system to predict outcome. <i>Vox Sang</i> 2006;90(1):45-52.	Small sample size

Excluded article	Reason for exclusion
Biss TT, Hanley JP. Recombinant activated factor VII (rFVIIa/NovoSeven) in intractable haemorrhage: use of a clinical scoring system to predict outcome [see comment]. <i>Vox Sanguinis</i> 2006;90(1):45-52.	Small sample size
Biss TT, Hanley JP. The use of recombinant factor VIIa in the management of major haemorrhage: Experience within the northern region of the UK. <i>British Journal of Haematology</i> 2005;129(Suppl 1):20.	Data combined for multiple conditions
Biss TT, Hanley JP. Use of recombinant factor VIIa (rFVIIa) in the management of intractable haemorrhage: a survey of current UK practice. <i>British Journal of Haematology</i> 2007;138(1):126-128.	Ineligible study design
Blansfield JS, Nekervis MA. A memorable Marine: the battle of coagulopathy. <i>Journal of Emergency Nursing</i> 2007;33(6):545-549.	Small sample size
Blasco V, Leone M, Visintini P, et al. Medical-surgical management of traumatic cardiac rupture: Relevance of recombinant activated factor VII. <i>Annales Francaises d'Anesthesie et de Reanimation</i> 2008;27(9):719-722.	Small sample size
Blatny J, Dusek L, Smid R, et al. "UniSeven" - Registry for life threatening bleeding treated with rFVIIa. Medical and technical background and first output. <i>Blood</i> 2004;104(11 Part 2):88B.	Data combined for multiple conditions
Blatt J, Gold SH, Wiley JM, et al. Off-label use of recombinant factor VIIa in patients following bone marrow transplantation. <i>Bone Marrow Transplantation</i> 2001;28(4):405-407.	Ineligible study design
Blonski W, Siropaides T, Reddy KR. Coagulopathy in liver disease. <i>Current Treatment Options in Gastroenterology</i> 2007;10(6):464-473.	Ineligible study design
Boehlen F, Morales MA, Fontana P, et al. Prolonged treatment of massive postpartum haemorrhage with recombinant factor VIIa: case report and review of the literature. <i>Bjog</i> 2004;111(3):284-287.	Ineligible study design
Boffard KD, Riou B, Warren B, et al. Recombinant factor VIIa as adjunctive therapy for bleeding control in severely injured trauma patients: two parallel randomized, placebo-controlled, double-blind clinical trials. <i>J Trauma</i> 2005;59(1):8-15; discussion 15-8.	Duplicate
Boldt J, Papsdorf M. Modern therapeutical strategies in intensive care medicine - are they established in Germany? Results from a questionnaire. <i>DMW Deutsche Medizinische Wochenschrift</i> 2005;130(3):87-91.	Ineligible study design
Bontempo FA, Friedlander L, Van Thiel DH. The use of recombinant human factor VIIa concentrate for short term reversal of coagulopathy in patients undergoing liver biopsy. <i>Blood</i> 2003;102(11):106b.	Ineligible study design
Bormanis J. Development of a massive transfusion protocol. <i>Transfusion & Apheresis Science</i> 2008;38(1):57-63.	Ineligible study design
Bosch J, Abraldes JG. Management of gastrointestinal bleeding in patients with cirrhosis of the liver. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):8-12.	Ineligible study design
Bosch J, Thabut D, Albillos A, et al. Recombinant factor VIIA (RFVIIA) for active variceal bleeding in patients with advanced cirrhosis: A multi-centre randomized double-blind placebo-controlled trial. <i>Journal of Hepatology</i> 2007;46(Suppl 1):S295-S296.	Duplicate
Bosch J, Thabut D, Albillos A, et al. Recombinant factor VIIa for variceal bleeding in patients with advanced cirrhosis: A randomized, controlled trial. <i>Hepatology</i> 2008;47(5):1604-1614.	Duplicate
Bosch J, Thabut D, Albillos A, et al. Recombinant factor VIIa (Rfviiia) for active variceal bleeding in patients with advanced cirrhosis: A multi-center randomised double-blind placebo-controlled trial. <i>Gastroenterology</i> . 2007;132(4 Suppl 2):A728.	Duplicate
Boshkov LK, Thomas G, Kirby A, et al. Normalization of the Thromboelastogram (TEG) and Cessation of Bleeding after Infusion of Recombinant Factor VIIa (rFVIIa) in a Child with Pulmonary Hemorrhage and Complex Coagulopathy Post Tissue Plasminogen Activator (TPA) Infusion. <i>Blood</i> 2002;100(11):Abstract No. 3901.	Ineligible study design
Bosinski TJ, El Solh AA. Recombinant factor VIIa, its clinical properties, and the tissue factor pathway of coagulation. <i>Mini-Reviews in Medicinal Chemistry</i> . 2006;6(10):1111-1117.	Ineligible study design
Bouma LS, Bolte AC, van Geijn HP, et al. Use of recombinant activated factor VII in massive postpartum haemorrhage. <i>European Journal of Obstetrics, Gynecology, & Reproductive Biology</i> 2008;137(2):172-177.	Ineligible study design
Bouma LS, Bolte AC, van Geijn HP. Use of recombinant activated factor VII in massive postpartum haemorrhage. <i>European Journal of Obstetrics, Gynecology, & Reproductive Biology</i> 2008;137(2):172-177.	Ineligible study design

Excluded article	Reason for exclusion
Bouwmeester FW, Jonkhoff AR, Verheijen RH, et al. Successful treatment of life-threatening postpartum hemorrhage with recombinant activated factor VII. <i>Obstet Gynecol</i> 2003;101(6):1174-1176.	Ineligible study design
Bowles KM, Callaghan CJ, Taylor AL, et al. Predicting response to recombinant factor VIIa in non-haemophiliac patients with severe haemorrhage [see comment]. <i>British Journal of Anaesthesia</i> 2006;97(4):476-481.	Small sample size
Brady KM, Easley RB, Tobias JD. Recombinant activated factor VII (rFVIIa) treatment in infants with hemorrhage. <i>Paediatr Anaesth.</i> 2006;16(10):1042-1046.	Small sample size
Brandsborg S, Sorensen B, Poulsen LH, et al. Recombinant activated factor VIIa in uncontrolled bleeding: a haemostasis laboratory study in non-haemophilia patients. <i>Blood Coagul Fibrinolysis</i> 2006;17(4):241-249.	Small sample size
Brenner B, Hoffman R, Balashov D, Control of bleeding caused by thrombocytopenia associated with hematologic malignancy: an audit of the clinical use of recombinant activated factor VII. <i>Clin Appl Thromb Hemost</i> 2005;11(4):401-410.	Ineligible study design
Brenner B, Hoffman R, Watson H, et al. Management of uncontrollable bleeding with recombinant factor VIIa (rFVIIa) in patients with thrombocytopenia associated with malignancy. <i>Pathophysiology of Haemostasis and Thrombosis</i> 2003;33(Suppl 1):73.	Ineligible study design
Brenner B, Pihusch M, Bacigalupo A, et al. Activated recombinant factor VII (rFVIIa/NovoSeven(R)) in the treatment of bleeding complications following hematopoietic stem cell transplantation (HSCT). <i>Blood</i> 2004;104(11).	Duplicate
Broderick J, Mayer SA, Brun NC, et al. Determinants of hemorrhage growth in a randomized trial of recombinant activated factor VII. <i>Journal of the Neurological Sciences</i> 2005;238(Suppl 1).	Duplicate
Broderick JP, Diringner MN, Hill MD, et al. Determinants of intracerebral hemorrhage growth: an exploratory analysis. <i>Stroke</i> 2007;38(3):1072-1075.	Duplicate
Broderick JP. Advances in the treatment of hemorrhagic stroke: a possible new treatment.[see comment]. <i>Cleveland Clinic Journal of Medicine</i> 2005;72(4):341-344.	Ineligible study design
Brose S, Sirbu H, Engel M, et al. Successful use of recombinant factor VIIa in a patient with intractable bleeding during extracorporeal membrane oxygenation. <i>Thorac Cardiovasc Surg</i> 2005;53(6):389-390.	Ineligible study design
Brown JB, Emerick KM, Brown DL, et al. Recombinant factor VIIa improves coagulopathy caused by liver failure. <i>Journal of Pediatric Gastroenterology & Nutrition</i> 2003;37(3):268-272.	Ineligible study design
Brown JL, Varma S, Morgan-Hughes NJ, et al. Thrombosis related to emergency factor VIIa treatment. <i>Anaesthesia</i> 2003;58(12):1245.	Ineligible study design
Brueckner S, Sedemund-Adib B, Malik E, et al. Treatment of a post partum bleeding complication with recombinant factor VIIa. <i>Blood</i> 2001;98(11 Part 2):80b.	Ineligible study design
Brun NC, Skolnick B. FAST: recombinant Factor VIIa in acute intracerebral haemorrhage. <i>Stroke Trials Directory, Internet Stroke Center: www.strokecenter.org/trials.</i> 2005.	Duplicate
Bryant P, Sunderland T, Mogul M. Sequential use of recombinant factor VIIa and FEIBA in a pediatric patient with disseminated intravascular coagulation. <i>Blood</i> 2006;108(11 Part 2):95B-96B.	Ineligible study design
Buckmiller LM, Richter GT, Waner M, et al. Use of recombinant factor VIIa during excision of vascular anomalies. <i>Laryngoscope</i> 2007;117(4):604-609.	Ineligible study design
Bui JD, Despotis GD, Trulock EP, et al. Fatal thrombosis after administration of activated prothrombin complex concentrates in a patient supported by extracorporeal membrane oxygenation who had received activated recombinant factor VII [see comment]. <i>Journal of Thoracic & Cardiovascular Surgery</i> 2002;124(4):852-854.	Small sample size
Burtelow M, Riley E, Druzin M, et al. How we treat: management of life-threatening primary postpartum hemorrhage with a standardized massive transfusion protocol. <i>Transfusion</i> 2007;47(9):1564-1572.	Ineligible study design
Busani S, Cavazzuti I, Marietta M, et al. Strategies to control massive abdominal bleeding. <i>Transplantation Proceedings</i> 2008;40(4):1212-1215.	Small sample size
Busani S, Marietta M, Pasetto A, et al. Use of recombinant factor VIIa in a thrombocytopenic patient with spontaneous intracerebral haemorrhage. <i>Thrombosis & Haemostasis</i> 2005;93(2):381-382.	Small sample size
Busani S, Semeraro G, Cantaroni C, et al. Recombinant activated factor VII in critical bleeding after orthotopic liver transplantation. <i>Transplantation Proceedings</i> 2008;40(6):1989-1990.	Small sample size

Excluded article	Reason for exclusion
Butcher K, Baird T, Parsons M, et al. Medical Management of Intracerebral Hemorrhage. <i>Neurosurgery Quarterly</i> . 2002;12(4):261-278.	Ineligible study design
Butenas S, Mann KG. Active tissue factor in blood? <i>Nat Med</i> 2004;10(11):1155-1156; author reply 1156.	Animal or in-vitro study
Butwick AJ, Riley ET, Ahonen J, et al. Recombinant factor VIIa for life-threatening post-partum haemorrhage. <i>Br J Anaesth</i> 2005;95(4):558; author reply 558.	Ineligible study design
Byhahn C. Reduced recombinant activated factor VII of the foreign blood requirement in polytraumatised patients? <i>Anaesthetist</i> 2006;55(5):578, 580.	Ineligible study design
Caldwell SH, Chang C, Macik BG. Recombinant activated factor VII (rFVIIa) as a hemostatic agent in liver disease: a break from convention in need of controlled trials. <i>Hepatology</i> 2004;39(3):592-598.	Ineligible study design
Caldwell SH, Chang C, Macik BG. Recombinant activated factor VII (rFVIIa) as a hemostatic agent in liver disease: A break from convention in need of controlled trials. <i>Hepatology</i> 39(3):592-598.	Ineligible study design
Caldwell SH, Hoffman M, Lisman T, et al. Coagulation disorders and hemostasis in liver disease: pathophysiology and critical assessment of current management. <i>Hepatology</i> 2006;44(4):1039-1046.	Ineligible study design
Campos M, Lima M, Morais S, et al. Clinical experience with rFVIIa as an universal haemostatic agent. <i>Haemostasis</i> 2000;30(Suppl 1):42-43.	Ineligible study design
Cantalapiedra A, Gutierrez O, Tortosa JI, et al. Oral anticoagulant treatment: risk factors involved in 500 intracranial hemorrhages. <i>J Thromb Thrombolysis</i> 2006;22(2):113-120.	No usable data
Capozzi JD, Rhodes R, Cornwall R. Bedside rationing. <i>J Bone Joint Surg Am</i> 2002;84-A(7):1279-1281.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Carbert S, Venn R. Recently published papers: out with the old and in with the new ... then something new for the old! <i>Critical Care (London, England)</i> 2005;9(3):238-240.	Ineligible study design
Carcao MD, Webert KE. On-label versus off-label use of recombinant activated factor VII: A comprehensive review of use in two Canadian centers. <i>Seminars in Hematology</i> . 2008;45(2 Suppl 1):S68-S71.	Ineligible study design
Carlbom DJ, Davidson BL. Pulmonary embolism in the critically ill. <i>Chest</i> 2007;132(1):313-324.	Ineligible study design
Carnazzo SA, Saitta R, Laurentini GM, et al. Use of recombinant activated factor VII in an elderly female undergoing acenocoumarol thromboprophylaxis requiring an emergency laparotomy. <i>J Thromb Thrombolysis</i> 2005;19(3):213-214.	Ineligible study design
Carr Jr ME, Martin EJ. Recombinant Factor VIIa: clinical applications for an intravenous hemostatic agent with broad-spectrum potential. <i>Expert Rev Cardiovasc Ther</i> 2004;2(5):661-674.	Ineligible study design
Cavallini A, Fanucchi S, Persico A. Warfarin-associated intracerebral hemorrhage. <i>Neurological Sciences</i> 2008;29(Suppl 2):S266-S268.	Ineligible study design
Celkan T, Alhaj S, Civilibal M, et al. Control of bleeding associated with hemophagocytic syndrome in children: an audit of the clinical use of recombinant activated factor VII. <i>Pediatr Hematol Oncol</i> 2007;24(2):117-121.	Ineligible study design
Cerny V, Blatny J, Dusek L, et al. Administration of recombinant activated factor VII in patients without hemophilia in the Czech Republic: analysis of selected data from uniseven register. <i>Crit Care Med</i> 2005;33(12):A46.	No usable data
Cervera JS, Andres Blasco CJ, Mena-Duran AV. Treatment of acute bleeding with recombinant factor VIIa in a patient with IgA deficit receiving anticoagulant therapy. <i>Acta Haematologica (Basel)</i> 2003;110(1):51-52.	Ineligible study design
Cervera JS, Mena-Duran AV, Piqueras CS. The use of recombinant factor VIIa in a patient with essential thrombocythaemia with uncontrolled surgical bleeding. <i>Thrombosis and Haemostasis</i> 2005;93(2):383-384.	Ineligible study design
Cetin H, Yalaz M, Akisu M, et al. The use of recombinant activated factor VII in the treatment of massive pulmonary hemorrhage in a preterm infant. <i>Blood Coagul Fibrinolysis</i> 2006;17(3):213-216.	Ineligible study design
Chai S, Macik BG. Experience with Recombinant Factor VIIa for Reversal of Coagulopathy before Invasive Procedures. <i>Blood</i> 2002;100(11):Abstract No. 3844.	Data combined for multiple conditions
Chalwin RP, Tiruvoipati R, Peek GJ, et al. Fatal thrombosis with activated factor VII in a paediatric patient on extracorporeal membrane oxygenation. <i>European Journal of Cardio-Thoracic Surgery</i> 2008;34(3):685-686.	Small sample size

Excluded article	Reason for exclusion
Champion HR, Fingerhut A, Escobar MA, et al. The role of data and safety monitoring in acute trauma resuscitation research. <i>Journal of the American Coll777e of Surgeons</i> 2007;204(1):73-83.	Duplicate
Chang GY. Hematoma growth is a determinant of mortality and poor outcome after intracerebral hemorrhage.[comment]. <i>Neurology</i> 2007;68(6):471-472; author reply 472.	Small sample size
Chanimov M, Ben-Shlomo I, Chayen B, et al. Amniotic fluid embolism: a plea for better brain protection. <i>Israel Medical Association Journal: Imaj</i> 2008;10(2):154-155.	Ineligible study design
Chauleur C, Cochery-Nouvellon E, Mercier E, et al. Analysis of the venous thromboembolic risk associated with severe postpartum haemorrhage in the NOHA First cohort. <i>Thrombosis & Haemostasis</i> 2008;100(5):773-779.	No usable data
Chawla M, Voigt LP, Pastores SM, et al. Recombinant activated factor VII in critically ill cancer patients with severe hemorrhage. <i>Chest</i> 2007;132(4 Suppl S):563S.	Ineligible study design
Cheng CAY, Ho AMH. Use of recombinant activated factor VII after axillofemoral bypass grafting. <i>Anaesthesia & Intensive Care</i> 2006;34(3):375-378.	Ineligible study design
Cheng Y, Baxter MS, Schroeder WS, et al. Clinical outcomes of off-label use of recombinant activated factor VII (rFVIIa) at teaching hospitals affiliated with a medical school. <i>Blood</i> 2006;108(11 Part 2):86B.	Data combined for multiple conditions
Cherfan A, Arabi Y, Al Askar A, et al. Recombinant activated factor VII treatment of retroperitoneal hematoma in a patient with renal failure receiving enoxaparin and clopidogrel. <i>Pharmacotherapy</i> 2007;27(5):755-759.	Ineligible study design
Cheung RTF. Update on medical and surgical management of intracerebral hemorrhage. <i>Reviews on Recent Clinical Trials</i> 2007;2(3):174-181.	Ineligible study design
Chiara O, Cimbanassi S, Briosci PR, et al. Treatment of critical bleeding in trauma patients. <i>Minerva Anestesiologica</i> 2006;72(6):383-387.	Small sample size
Chin C. Recombinant activated factor VII. <i>Paediatr Anaesth</i> 2006;16(9):907-909.	Ineligible study design
Chino J, Paolini D, Tran A, et al. Recombinant activated factor VII as an adjunct to packing for liver injury with hepatic venous disruption. <i>Am Surg</i> 2005;71(7):595-597.	Small sample size
Choudhuri S, Kelsey P, Cahalin P, et al. Study on the role of recombinant factor VIIa in the management of intractable blood loss in patients without inherited bleeding disorder in a UK district general hospital. <i>Blood</i> 2007;110(11 Part 1):925A.	Data combined for multiple conditions
Christensen MC, Mayer SA, Ferran JM, et al. Depressed mood after intracerebral hemorrhage: the FAST trial. <i>Cerebrovascular Diseases</i> 2009;27(4):353-360.	Not on rFVIIa
Christians K, Brasel K, Garlitz J, et al. The use of recombinant activated factor VII in trauma-associated hemorrhage with crush injury. <i>J Trauma</i> 2005;59(3):742-746.	Small sample size
Chuansumrit A, Chantarojanasiri T, Isarangkura P, et al. Recombinant activated factor VII in children with acute bleeding resulting from liver failure and disseminated intravascular coagulation. <i>Blood Coagul Fibrinolysis</i> . 2000;11(Suppl 1):S101-S105.	Ineligible study design
Chuansumrit A, Nuntnarumit P, Okascharoen C, et al. The use of recombinant activated factor VII to control bleeding in a preterm infant undergoing exploratory laparotomy. <i>Pediatrics</i> 2002;110(1 Pt 1):169-171.	Ineligible study design
Chuansumrit A, Tangnararatchakit K, Lektakul Y, et al. The use of recombinant activated factor VII for controlling life-threatening bleeding in Dengue Shock Syndrome. <i>Blood Coagulation & Fibrinolysis</i> 2004;15(4):335-342.	Ineligible study design
Chuansumrit A, Tangnararatchakit K, Lektrakul Y, et al. Recombinant Activated Factor VII in Controlling Life-Threatening Bleeding in Dengue Shock Syndrome. <i>Blood</i> 2002;100(11):Abstract No. 3799.	Ineligible study design
Chuansumrit A, Teeraratkul S, Attanawanich S, et al. The use of recombinant activated factor VII for controlling bleeding in pediatric patients undergoing invasive surgeries. <i>Blood</i> 2004;104(11 Part 2):89B.	Data combined for multiple conditions
Chuansumrit A, Teeraratkul S, Tripongkaruna S, et al. The effectiveness of recombinant factor VIIa in the treatment of bleeding in pediatric patients: A ten-year experience from 1997 to 2007. <i>Blood</i> 2007;110(11 Part 2):55B.	Ineligible study design
Chuansumrit A, Treepongkaruna S, Hongeng S, et al. Recombinant factor VIIa combined with fresh frozen plasma in restoring hemostasis for invasive procedures in patients with liver diseases. <i>Hepatology</i> 2001;34(4 Pt 2):532A.	Unable to obtain publication
Chuansumrit A, Treepongkaruna S, Phuapradit P. Combined fresh frozen plasma with recombinant factor VIIa in restoring hemostasis for invasive procedures in children with liver diseases. <i>Thromb Haemost</i> 2001;85(4):748-749.	Ineligible study design

Excluded article	Reason for exclusion
Ciacma A, Debski R, Malinowski A, et al. Recombinant Activated Factor VII (rFVIIa) Effectively Controls Bleeding in Gynecologic Surgery: A Report on Four Cases. <i>Journal of Gynecologic Surgery</i> 2005;21:13-20.	Ineligible study design
Cimic N, Tulleken JE, Zijlstra JG, et al. Recombinant factor VIIa for refractory hemorrhage after lung transplantation. <i>Transplantation</i> 2005;79(6):741-742.	Ineligible study design
Clark AD, Gordon WC, Walker ID, et al. 'Last-ditch' use of recombinant factor VIIa in patients with massive haemorrhage is ineffective. <i>Vox Sanguinis</i> 2004;86(2):120-124.	Small sample size
Clarke P, Shearer MJ. Vitamin K deficiency bleeding after missed prophylaxis: rapid synergistic effect of vitamin K therapy on hemostasis [comment]. <i>Southern Medical Journal</i> 2007;100(6):612-613.	Ineligible study design
Colina CM, Venkateswarlu D, Duke R, et al. What causes the enhancement of activity of factor VIIa by tissue factor? <i>Journal of Thrombosis & Haemostasis</i> 2006;4(12):2726-2729.	Not on rFVIIa
Conen A, Weisser M, Tsakiris DA, et al. Failure of recombinant factor VIIa in a patient with severe polymicrobial sepsis and postoperative uncontrolled intraabdominal bleeding. <i>BMC Infect Dis</i> 2007;7:34.	Ineligible study design
Conesa V, Navarro-Ruiz A, Borrás-Blasco J, et al. Recombinant factor VIIa is an effective therapy for abdominal surgery and severe thrombocytopenia: a case report. <i>Int J Hematol</i> 2005;81(1):75-76.	Ineligible study design
Conti S, La Torre D, Gambelunghe G, et al. Successful treatment with rFVIIa of spontaneous intracerebral hemorrhage in a patient with mechanical prosthetic heart valves. <i>Clinical & Laboratory Haematology</i> 2005;27(4):283-285.	Small sample size
Controlled off-label use of recombinant activated factor VII (NovoSeven) can build evidence base. <i>Cardiovascular Journal of Africa</i> 2008;19(1):52-54.	Ineligible study design
Coppola A, De Simone C, Palmieri NM, et al. Recombinant activated factor VII for hemostatic cover of orthopedic interventions in a girl with thrombocytopenia with absent radii syndrome. <i>Blood Coagulation & Fibrinolysis</i> 2007;18(2):199-201.	Ineligible study design
Corbett SM, Rebeck JA. Medication-related complications in the trauma patient. <i>Journal of Intensive Care Medicine</i> 2008;23(2):91-108.	Ineligible study design
Cordonnier C. From trials to "real life": necessity of efficacy [comment]. <i>Stroke</i> 2005;36(12):2527.	Ineligible study design
Cosmi B. Review: recombinant factor VIIa does not differ from placebo for prevention or treatment of bleeding in patients without hemophilia [comment]. <i>ACP Journal Club</i> 2007;147(3):70.	Ineligible study design
Craxi A, Camma C, Giunta M. Clinical aspects of bleeding complications in cirrhotic patients. <i>Blood Coagulation & Fibrinolysis</i> 2000;11 Suppl 1:S75-S79.	Ineligible study design
Criddle LM. Recombinant factor VIIa and the trauma patient. <i>Journal of Emergency Nursing</i> 2006;32(5):404-408.	Ineligible study design
Cruz-Flores S. Myocardial injury in patients with intracerebral hemorrhage treated with recombinant factor VIIa [comment]. <i>Neurology</i> 2007;68(20):1750-1751; author reply 1751.	Ineligible study design
Cruz-Flores S. Unexpected posthemorrhagic hydrocephalus in patients treated with rFVIIa. <i>Neurology</i> 2007;68(13):1084; author reply 1084-5.	Ineligible study design
Cruz-Flores S. Unexpected posthemorrhagic hydrocephalus in patients treated with rFVIIa.[comment]. <i>Neurology</i> 2007;68(13):1084; author reply 1084-5.	Ineligible study design
Csermely L, Jaafar H, Kristensen J, et al. Strongyloides hyper-infection causing life-threatening gastrointestinal bleeding. <i>World Journal of Gastroenterology</i> 2006;12(39):6401-6404.	Ineligible study design
Culic S, Kuljis D, Armanda V, et al. Successful management of bleeding with recombinant factor VIIa (NovoSeven) in a patient with Burkitt lymphoma and thrombosis of the left femoral and left common iliac veins. <i>Pediatr Blood Cancer</i> 2007;49(3):332-335.	Ineligible study design
Culic S. Recombinant factor VIIa for refractive haemorrhage in autoimmune idiopathic thrombocytopenic purpura. <i>British Journal of Haematology</i> 2003;120(5):909-910.	Ineligible study design
Culley CM, Spiro RM, Ragni MV, et al. Off-label use of recombinant factor VIIa in non-hemophilic patients. <i>Pharmacotherapy</i> 2004;24(10):1437.	Other: unpublished data
Culligan DJ, Salamat A, Tait J, et al. Use of recombinant factor VIIa in life-threatening bleeding following autologous peripheral blood stem cell transplantation complicated by platelet refractoriness. <i>Bone Marrow Transplant</i> 2003;31(12):1183-1184.	Ineligible study design
da Silva Viana J. Recombinant factor VIIa in major abdominal surgery and liver transplantation. <i>Transplantation Proceedings</i> 2006;38(3):818-819.	Ineligible study design

Excluded article	Reason for exclusion
Da'as N, Misgav M, Kalish Y, et al. Recombinant factor VIIa for rapid reversal of anticoagulant effect in patients with intracranial hemorrhage: the Israeli experience and review of the literature. <i>Israel Medical Association Journal: Imaj</i> 2006;8(11):807-811.	Small sample size
Dager W, Regalia R, Williamson D, et al. Low dose recombinant factor VIIa in trauma or coagulopathy. <i>Pharmacotherapy</i> . 2004;24(10):1429.	Small sample size
Dager WE, King JH, Regalia RC, et al. Reversal of elevated international normalized ratios and bleeding with low-dose recombinant activated factor VII in patients receiving warfarin. <i>Pharmacotherapy</i> . 2006;26(8):1091-1098.	Data combined for multiple conditions
Danilos J, Goral A, Paluszkiewicz P, et al. Successful treatment with recombinant factor VIIa for intractable bleeding at pelvic surgery. <i>Obstet Gynecol</i> 2003;101(6):1172-1173.	Ineligible study design
Dao A, Tuan B, Carlson N. Reversal of a potent investigational anticoagulant: idraparinix with recombinant factor VIIa. <i>Am J Med</i> 2005;118(10):1172-1173.	Ineligible study design
Dargaud Y, Bordet JC, Lienhart A, et al. Use of the thrombin generation test to evaluate response to treatment with recombinant activated factor VII. <i>Seminars in Hematology</i> 2008;45(2 Suppl 1):S72-S73.	Animal or in-vitro study
Dart BWIV, Cockerham WT, Torres C, et al. A novel use of recombinant factor VIIa in HELLP syndrome associated with spontaneous hepatic rupture and abdominal compartment syndrome. <i>Journal of Trauma Injury Infection and Critical Care</i> 2004;57(1):171-174.	Ineligible study design
Das P, Carcao M, Hitzler J. Use of recombinant factor VIIa prior to lumbar puncture in pediatric patients with acute leukemia. <i>Pediatr Blood Cancer</i> 2006;47(2):206-209.	Ineligible study design
Davalos A, Fisher M. Emerging therapies for cerebrovascular disorders. <i>Stroke</i> 2005;36(2):208-210.	Ineligible study design
Davis MC, Andersen NE, Johansson P, et al. Use of thromboelastograph and factor VII for the treatment of postoperative bleeding in a pediatric patient on ECMO after cardiac surgery. <i>J Extra Corpor Technol</i> 2006;38(2):165-167.	Small sample size
Davis S, Mayer S, Brun N, et al. Safety of activated recombinant factor VII in acute intracerebral hemorrhage: results of two multi-center placebo-controlled trials. <i>Internal Medicine Journal</i> 2004;34(1-2).	Duplicate
Davis SM, Broderick J, Hennerici M, et al. Hematoma growth is a determinant of mortality and poor outcome after intracerebral hemorrhage. <i>Neurology</i> 2006;66(8):1175-1181.	Ineligible study design
Davis SM, Broderick J, Hennerici M, et al. Hematoma growth is a determinant of mortality and poor outcome after intracerebral hemorrhage [see comment]. <i>Neurology</i> 2006;66(8):1175-1181.	Ineligible study design
Davis SM, Kaye AH. Therapy for intracerebral hemorrhage. <i>J Clin Neurosci</i> 2005;12(3):219-20.	Ineligible study design
De Fabritiis P, Dentamaro T, Picardi A, et al. Recombinant factor VIIa for the management of severe hemorrhages in patients with hematologic malignancies. <i>Haematologica</i> . 2004;89(2):243-245.	Ineligible study design
De Gasperi A, Baudo F. Use of recombinant factor VIIa during orthotopic liver transplantation. <i>Liver Transpl</i> 2006;12(7):1176-7; author reply 1178-1179.	Ineligible study design
De Gasperi A. Intraoperative use of recombinant activated factor VII (rFVIIa). <i>Minerva Anesthesiol</i> 2006;72(6):489-494.	Ineligible study design
de Miranda PA, de Miranda PAP. "Evaluation of off-label recombinant activated factor VII for multiple indications in children" by Reiter et al. [comment]. <i>Clinical & Applied Thrombosis/Hemostasis</i> 2008;14(2):247; author reply 247.	Ineligible study design
de Miranda PAP. "Evaluation of off-label recombinant activated factor VII for multiple indications in children" by Reiter et al. <i>Clinical & Applied Thrombosis/Hemostasis</i> 2008;14(2):247; author reply 247.	Ineligible study design
De Santiago J, Martinez-Garcia E, Giron J, et al. Prophylactic recombinant factor VIIa administration to an infant with congenital systemic juvenile xanthogranuloma. <i>Paediatr Anaesth</i> 2006;16(9):974-976.	Ineligible study design
de Wolf JT, Hendriks HG, Meijer K, et al. Impressive reduction of blood requirements in orthotopic liver transplantation due to recombinant factor VIIa (rFVIIa, NovoSeven). <i>Transfusion (Bethesda)</i> 1999;39(10 Suppl):87S.	Small sample size
Dejgaard A. Update on Novo Nordisk's clinical trial programme on NovoSeven. <i>Blood Coagulation & Fibrinolysis</i> 2003;14 Suppl 1:S39-S41.	Ineligible study design
DelGaudio JM, Martinez EJ. Endoscopic sinus surgery in patients with chronic hepatic failure awaiting liver transplant. <i>American Journal of Rhinology</i> 2004;18(4):253-258.	Ineligible study design

Excluded article	Reason for exclusion
Dell'Era A, Bosch J. Treatment of variceal bleeding in patients with cirrhosis of the liver. <i>Clinical Intensive Care</i> 2005;16(3/4):111-119.	Ineligible study design
Dell'Era A, de Franchis R, Iannuzzi F. Acute variceal bleeding: pharmacological treatment and primary/secondary prophylaxis. <i>Best Pract Res Clin Gastroenterol</i> 2008;22(2):279-294.	Ineligible study design
Dell'Utri D, Passariello M. The use of recombinant-activated factor VII to successfully control postoperative critical bleeding after emergency repair of ruptured abdominal aortic aneurysm in a noncoagulopathic patient. <i>J Cardiothorac Vasc Anesth</i> 2006;20(4):570-572.	Ineligible study design
DeLoughery TG. Management of bleeding emergencies: when to use recombinant activated factor VII. <i>Expert Opin Pharmacother</i> 2006;7(1):25-34.	Ineligible study design
Dement'eva I, Gladysheva VG, Charnaia MA, et al. [On the mechanism of action of recombinant activated factor VII in massive non-hemophylic bleeding in cardio-surgical patients]. <i>Vestn Ross Akad Med Nauk</i> 2006(12):21-25.	Foreign language
Demytyeva II, Gladysheva VG, Charnaya MA, et al. Influence of recombinant activated factor VIIa thrombocytic hemostasis. <i>Gematologiya i Transfuziologiya</i> 2005;50(6):12-15.	Foreign language
Demytyeva II, Sandrikov VA, Charnaya MA, et al. The "NovoSeven" (rFVIIa) hemostatic in massive hemorrhages in patients operated on the heart and aorta. <i>Anesteziologiya i Reanimatologiya</i> 2004(5):11-13.	Foreign language
Dempfle CE, Borggreffe M. Acidosis and impaired blood coagulation: what and how to correct before using recombinant human factor VIIa. <i>Crit Care Med</i> 2007;35(6):1627-1629.	Animal or in-vitro study
Dempfle CE, Borggreffe M. Disseminated intravascular coagulation. <i>Intensivmedizin und Notfallmedizin</i> 2006;43(2):103-110.	Ineligible study design
Dempfle CE. Hemostatic changes in sepsis: Cause or consequence? <i>Intensiv- und Notfallbehandlung</i> 2003;28(1):26-36.	Ineligible study design
Dentali F, Ageno W, Crowther M. Treatment of coumarin-associated coagulopathy: a systematic review and proposed treatment algorithms. <i>J Thromb Haemost</i> 2006;4(9):1853-1863.	Ineligible study design
Dentamaro T, Cudillo L, Picardi A, et al. Recombinant factor VIIa in the management of severe hemorrhage in patients with hematologic malignancies. <i>Blood</i> 2002;100(11):Abstract No. 3316.	Ineligible study design
DeSancho MT, Rand JH. Bleeding and thrombotic complications in critically ill patients with cancer. <i>Crit Care Clin</i> 2001;17(3):599-622.	Ineligible study design
Despotis G, Avidan M, Lublin DM. Off-label use of recombinant factor VIIa concentrates after cardiac surgery [comment]. <i>Annals of Thoracic Surgery</i> 2005;80(1):3-5.	Ineligible study design
Despotis G, Eby C, Lublin DM. A review of transfusion risks and optimal management of perioperative bleeding with cardiac surgery. <i>Transfusion</i> 2008;48(1 Suppl):2S-30S.	Ineligible study design
Despotis G, Renna M, Eby C. Risks associated with bleeding and transfusion: rationale for the optimal management of bleeding after cardiac surgery. <i>European Journal of Anaesthesiology</i> 2007;24(Suppl 40):15-36.	Ineligible study design
Despotis G. The role of diagnostic testing to identify congenital vs acquired disorders of hemostasis and to optimize the management of perioperative bleeding. <i>Vox Sanguinis</i> 2005;89(Suppl 1):3-4.	Ineligible study design
Detry O, De Roover A, Delwaide J, et al. Liver transplant in Jehovah's witnesses. <i>Hepatology</i> 2002;36(4 Part 2):671A.	Small sample size
Detry O, De Roover A, Honore P. Prevention and treatment of major blood loss [comment]. <i>New England Journal of Medicine</i> 2007;357(12):1261; author reply 1261.	Ineligible study design
Deveras RAE, Kessler CM. Recombinant factor VIIa (rFVIIa) successfully and rapidly corrects the excessively high international normalized ratios (INR) and prothrombin times induced by warfarin. <i>Blood</i> 2000;96(11 Part 1):638a.	Ineligible study design
Deveras RAE, Kessler CM. Reversal of warfarin-induced excessive anticoagulation with recombinant human factor VIIa concentrate [see comment] [summary for patients in <i>Ann Intern Med</i> 2002 Dec 3;137(11):141; PMID: 12459002]. <i>Annals of Internal Medicine</i> 2002;137(11):884-888.	Ineligible study design
Di Biaceglie AM, Richart JM. Spontaneous retroperitoneal and rectus muscle hemorrhage as a potentially lethal complication of cirrhosis. <i>Liver International</i> 2006;26:1291-1293.	Ineligible study design
DiDomenico RJ, Massad MG, Kpodonu J, et al. Use of recombinant activated factor VII for bleeding following operations requiring cardiopulmonary bypass. <i>Chest</i> 2005;127(5):1828-1835.	Small sample size

Excluded article	Reason for exclusion
Dietrich W, Spannagl M. Caveat against the use of activated recombinant factor VII for intractable bleeding in cardiac surgery. <i>Anesth Analg</i> 2002;94(5):1369-1370; author reply 1370-1371.	Ineligible study design
Dincer AP, Abu-Hajir M, Christians KK, et al. Human recombinant activated factor seven, novoseven (rVIIa), in the management of massive bleeding despite adequate resuscitation in major trauma. <i>Blood</i> 2002;100(11):Abstract No. 3918.	Small sample size
Diringer MN, Aiyagari V, Shackelford AM, et al. Use of recombinant factor VIIa in patients with warfarin-associated intracranial hemorrhage. <i>Blood</i> 2003;102(11):109b.	Duplicate
Diringer MN, Christensen MC, Ferran JM, et al. Recombinant activated factor VII in the treatment of acute intracerebral haemorrhage: implications for health-related quality of life. <i>International Journal of Stroke</i> 2006;1(Suppl 1).	Not on rFVIIa
Diringer MN, Ferran JM, Broderick J, et al. Impact of recombinant activated factor VII on health-related quality of life after intracerebral hemorrhage. <i>Cerebrovasc Dis</i> 2007;24(2-3):219-225.	Duplicate
Diringer MN, Mayer SA, Brun NC, et al. Safety profile of recombinant factor VIIa in patients with intracerebral haemorrhage. <i>European Journal of Neurology</i> 2006;13(Suppl 2):9.	Ineligible study design
Diringer MN, Skolnick BE, Mayer SA, et al. Risk of thromboembolic events in controlled trials of rFVIIa in spontaneous intracerebral hemorrhage. <i>Stroke</i> 2008;39(3):850-856.	Ineligible study design
Dissemination CfRa. Efficacy and safety of recombinant activated factor VII in major surgical procedures: systematic review and meta-analysis of randomized clinical trials (Provisional abstract). <i>Database of Abstracts of Reviews of Effects</i> 2009(1).	Ineligible study design
Dissemination CfRa. Efficacy and safety of recombinant activated factor VII in major surgical procedures: systematic review and meta-analysis of randomized clinical trials (Structured abstract). <i>Database of Abstracts of Reviews of Effects</i> 2009(3).	Duplicate
Dissemination CfRa. Evidence for the use of recombinant factor VIIa in the prevention and treatment of bleeding in patients without hemophilia (Brief record). <i>Database of Abstracts of Reviews of Effects</i> 2009(3).	Duplicate
Dissemination CfRa. Off-label use of recombinant factor VIIa for treatment of haemorrhage: results from randomized clinical trials (Provisional abstract). <i>Database of Abstracts of Reviews of Effects</i> 2009(3).	Duplicate
Dissemination CfRa. Potential role of recombinant activated factor VII for the treatment of severe bleeding associated with disseminated intravascular coagulation: a systematic review (Provisional abstract). <i>Database of Abstracts of Reviews of Effects</i> 2009(1).	Ineligible study design
Dissemination CfRa. Recombinant activated factor VII as a general haemostatic agent: evidence-based efficacy and safety (Provisional abstract). <i>Database of Abstracts of Reviews of Effects</i> 2009(1).	Ineligible study design
Dissemination CfRa. Recombinant activated factor VII in cardiac surgery: a systematic review (Structured abstract). <i>Database of Abstracts of Reviews of Effects</i> 2009(1).	Ineligible study design
Dissemination CfRa. Recombinant activated factor VIIa for the treatment of bleeding in major abdominal surgery including vascular and urological surgery: a review and meta-analysis of published data (Provisional abstract). <i>Database of Abstracts of Reviews of Effects</i> 2009(3).	Duplicate
Dissemination CfRa. Special report: recombinant activated factor VII for uncontrolled bleeding in non-hemophiliac patients (Provisional abstract). <i>Database of Abstracts of Reviews of Effects</i> 2009(1).	Ineligible study design
Dissemination CfRa. Use of recombinant activated factor VII in patients without hemophilia: a meta-analysis of randomized control trials (Provisional abstract). <i>Database of Abstracts of Reviews of Effects</i> 2009(3).	Duplicate
Dominguez TE, Mitchell M, Friess SH, et al. Use of recombinant factor VIIa for refractory hemorrhage during extracorporeal membrane oxygenation. <i>Pediatric Critical Care Medicine</i> 2005;6(3):348-351.	Small sample size
Duchesne JC, Mathew KA, Marr AB, et al. Current evidence based guidelines for factor VIIa use in trauma: the good, the bad, and the ugly. <i>American Surgeon</i> 2008;74(12):1159-1165.	Ineligible study design
Duffy MR. Guidelines for use of recombinant factor VIIa in life-threatening post-partum haemorrhage. <i>Int J Obstet Anesth</i> 2007;16(3):299-300; author reply 300.	Ineligible study design
Duffy MR. Massive obstetric haemorrhage: arterial embolisation vs rFVIIa. <i>Anaesthesia</i> 2006;61(10):1010; author reply 1010-1011.	Ineligible study design

Excluded article	Reason for exclusion
Duffy MR. Should recombinant factor VIIa be used for the treatment of patients with severe blunt trauma? <i>British Journal of Hospital Medicine</i> 2007;68(12):688.	Ineligible study design
Duncan A, Benson L, Critz A, Abshire T. Neonatal coagulopathy treatment with rFVIIa. <i>Pediatric Research</i> 2001;49(4 Part 2):290A.	Ineligible study design
Duncan A, Martinez EJ. Recombinant FVIIa(Novoseven)treatment of hepatic coagulopathies. <i>Hepatology</i> . 2002;36(4 Part 2):515A.	Ineligible study design
Dunkley S, Cameron PA, Phillips LE, et al. The use of recombinant activated factor VII in Australia and New Zealand. <i>Blood</i> 2006;108(11 Part 2):84B.	Data combined for multiple conditions
Dunkley S, Street A. Is there a high thrombosis rate associated with recombinant factor VIIa use in intractable hemorrhage in Australia? <i>Journal of Thrombosis & Haemostasis</i> 2004;2(10):1852-1853.	No usable data
Dunkley SM, Mackie F. Recombinant factor VIIa used to control massive haemorrhage during renal transplantation surgery; vascular graft remained patent. <i>Hematology</i> 2003;8(4):263-264.	Ineligible study design
Dunning J, Versteegh M, Fabbri A, et al. Guideline on antiplatelet and anticoagulation management in cardiac surgery. <i>European Journal of Cardio-Thoracic Surgery</i> 2008;34(1):73-92.	Ineligible study design
Dutton RP, Hess JR, Scalea TM. Recombinant factor VIIa for control of hemorrhage: early experience in critically ill trauma patients. <i>J Clin Anesth</i> 2003;15(3):184-188.	Small sample size
Dutton RP, Stein DM, Hess JR, Scalea TM. Recombinant factor VIIa and thromboembolic events.[comment]. <i>JAMA</i> . 2006;296(1):43-4; author reply 44.	Ineligible study design
Dutton RP, Stein DM. The use of factor VIIa in haemorrhagic shock and intracerebral bleeding. <i>Injury</i> 2006;37(12):1172-1177.	Ineligible study design
Dutton RP. Factor VII and the brain: time to get this research done! <i>Critical Care (London, England)</i> . 2007;11(4):161.	Ineligible study design
Dutton RP. Goals of therapy in common bleeding emergencies. <i>Pharmacotherapy</i> 2007;27(9 Pt 2):85S-92S.	Ineligible study design
Dyggve H. Prothrombin and proconvertin in the newborn and during the first year of life. <i>Acta Paediatrica</i> 1958;47(3):251-259.	Not on rFVIIa
Dzik WH, Grabowski EF, Feng S, et al. Preliminary experience with rFVIIa in children undergoing orthotopic liver transplantation. <i>Blood</i> 2001;98(11 Part 2):104b.	Small sample size
Dzik WH. Off-label reports of new biologics: exciting new therapy or dubious research? Examples from recombinant activated factor VII. <i>J Intensive Care Med</i> 2006;21(1):54-59.	Ineligible study design
Earnshaw SR, Joshi AV, Wilson MR, Rosand J. Cost-effectiveness of recombinant activated factor VII in the treatment of intracerebral haemorrhage. <i>Stroke</i> 37(11):2751-2758.	Ineligible study design
Earnshaw SR, Joshi AV, Wilson MR, et al. Cost-effectiveness of recombinant activated factor VII in the treatment of intracerebral hemorrhage. <i>Stroke</i> 2006;37(11):2751-2758.	Duplicate
Earnshaw SR, Wilson MR, Joshi AV. The effect of recombinant activated factor VII in the treatment of intracerebral hemorrhage on health plan budgets. <i>Manag Care Interface</i> 2006;19(11):39-45.	Ineligible study design
Egan JR, Lammi A, Schell DN, et al. Recombinant activated factor VII in paediatric cardiac surgery. <i>Intensive Care Medicine</i> 2004;30(4):682-685.	Small sample size
Ehtisham A, Taylor S, Klein MW. The effects of a recombinant human coagulation factor VII, novoseven 50 ug/kg in patients with intracerebral hemorrhage: A case series. <i>European Journal of Neurology</i> 2007;14(Suppl 1):166.	Small sample size
Eikelboom J, Bird R, Blythe D, et al. Recombinant activated factor VII for massive hemorrhage in non-hemophilia patients: The Australian experience. <i>Blood</i> 2002;100(11):Abstract No. 2800.	Ineligible study design
Eikelboom JW, Bird R, Blythe D, et al. Recombinant activated factor VII for the treatment of life-threatening haemorrhage. <i>Blood Coagulation & Fibrinolysis</i> 2003;14(8):713-717.	Data combined for multiple conditions
Ejlertsen E, Melsen T, Ingerslev J, et al. Recombinant activated factor VII (rFVIIa) acutely normalizes prothrombin time in patients with cirrhosis during bleeding from oesophageal varices. <i>Scandinavian Journal of Gastroenterology</i> 2001;36(10):1081-1085.	Ineligible study design
El Accaoui R, Isma'eel H, Khalil PB, et al. A review of the off-label use of recombinant activated factor VII in a developing country tertiary care center. <i>Blood Coagulation & Fibrinolysis</i> 2006;17(8):647-650.	Small sample size
El Kinge AR, Mahfouz RA, Shamseddine AI, et al. Recombinant activated factor VII for intractable bleeding post splenectomy in a patient with myeloproliferative disorder. <i>Blood Coagul Fibrinolysis</i> 2007;18(6):577-579.	Ineligible study design

Excluded article	Reason for exclusion
Eller P, Pechlaner C, Wiedermann C. Ineffective off-label use of recombinant activated factor VII in a case of bone-marrow transplantation-related gastrointestinal bleeding. <i>Thrombosis Journal [Electronic Resource]</i> 2006;4:1.	Ineligible study design
Emlet LL, Crippen D. Early recombinant activated factor VII for intracerebral hemorrhage reduced hematoma growth and mortality, while improving functional outcomes. <i>Crit Care</i> 2006;10(1):304.	Ineligible study design
Engelhardt K, Brenneis C, Pfausler B, et al. rFVII(a) - for acute rebleeding of a cerebral cavernous malformation. <i>European Journal of Neurology</i> 2007;14(1):117-120.	Small sample size
Engelhardt K, Brenneis C, Pfausler B, et al. rFVIIa--for acute rebleeding of a cerebral cavernous malformation. <i>European Journal of Neurology</i> 2007;14(1):117-120.	Small sample size
Enomoto TM, Thorborg P. Emerging off-label uses for recombinant activated factor VII: grading the evidence. <i>Critical Care Clinics</i> 2005;21(3):611-632.	Ineligible study design
Erhardttsen E. Ongoing NovoSeven trials. <i>Intensive Care Medicine</i> 2002;28 Suppl 2:S248-S255.	Ineligible study design
Erhardttsen E. Pharmacokinetics of recombinant activated factor VII (rFVIIa). <i>Seminars in Thrombosis and Hemostasis</i> 2000;26(4):385-391.	Animal or in-vitro study
Erhardttsen E. To general haemostasis--the evidence-based route. <i>Pathophysiology of Haemostasis & Thrombosis</i> 2002;32 Suppl 1:47-52.	Ineligible study design
Erikci AA, Ozturk A, Sayan O. Recombinant activated factor VII for severe uterine bleeding after chemotherapy in a woman with acute myeloid leukemia. <i>Blood Coagul Fibrinolysis</i> 2006;17(4):323-324.	Ineligible study design
Escobar M, Harvey RD. Experience with the use of recombinant factor VIIa in a University Hospital. <i>Blood</i> . 2001;98(11 Part 2):70b.	Ineligible study design
Escobar M, Melton LG, Thompson CM, et al. Dose response of recombinant factor VIIa in patients with hemophilia and liver disease. <i>Blood</i> 2001;98(11 Part 2):70b.	Ineligible study design
Escobar MA, Chong K, Hoots KW. Experience with the "Off label" use of recombinant factor VIIa in a university hospital. <i>Blood</i> 2004;104(11 Part 2):90B-91B.	Data combined for multiple conditions
Escobar MA. Reversal of coumarin-induced over-anticoagulation. <i>Br J Haematol</i> 2002;118(3):925-926; author reply 926.	Ineligible study design
Escolar G. New insights into the management of bleeding disorders. <i>Drug News & Perspectives</i> 2004;17(4):285-288.	Ineligible study design
Essex D, Bluth M, Gloster E, et al. Successful use of recombinant factor VIIa (rFVIIa) for trauma-associated massive hemorrhage. <i>Blood</i> 2000;96(11 Part 1):268a.	Small sample size
Estella A, Jareno A, Perez-Bello Fontaina L, Estella A, Jareno A, Perez-Bello Fontaina L. Intrapulmonary administration of recombinant activated factor VII in diffuse alveolar haemorrhage: a report of two case stories. <i>Cases Journal</i> 2008;1(1):150.	Ineligible study design
Evidence-based haemostasis. Proceedings of a symposium. Dublin, Ireland. November 9-11, 2001. <i>Pathophysiology of Haemostasis & Thrombosis</i> 2002;32 Suppl 1:V,1-52.	Ineligible study design
Ewanchuk MA, Hudson DA. Best evidence in anesthetic practice: recombinant activated factor VII for acute intracerebral hemorrhage: a promising therapy for a devastating problem?[comment]. <i>Canadian Journal of Anaesthesia</i> 2006;53(3):250-251.	Ineligible study design
Ewenstein BM. Continuous infusion of recombinant factor VIIa: continue or not? <i>Thromb Haemost</i> 2001;86(4):942-944.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Faber P, Craig WL, Duncan JL, et al. The successful use of recombinant factor VIIa in a patient with vascular-type Ehlers-Danlos syndrome. <i>Acta Anaesthesiol Scand</i> 2007;51(9):1277-1279.	Ineligible study design
Faber P, Reid C, El-Shafei H, et al. Case 5-2006: recombinant factor VIIa in the management of postoperative bleeding after repair for inadvertently thrombolysed acute type A aortic dissection. <i>Journal of Cardiothoracic & Vascular Anesthesia</i> 2006;20(5):736-741.	Small sample size
Factor VII improves outcome in stroke. <i>Pharmaceutical Journal</i> 2005;274(7339):263.	Ineligible study design
Fareed J, Bick RL, Kessler C, et al. Potential thrombogenic complications with the use of recombinant activated factor VII in combat trauma. <i>Clinical & Applied Thrombosis/Hemostasis</i> 2007;13(2):121-123.	Ineligible study design

Excluded article	Reason for exclusion
Farlo JN. Management of hemostasis during extreme normovolemic hemodilution in pediatric Jehovah's Witness Patients Undergoing High-Risk Surgical Procedures. Anesthesiology Abstracts of Scientific Papers Annual Meeting. 2003(2003):Abstract No. A-1425.	Ineligible study design
Farmer BM, Duthie E, Nelson LS. The dangers associated with fondaparinux (FDX) and reversal with recombinant factor VIIa. <i>Clinical Toxicology</i> 2008;46(7):641.	Ineligible study design
Farrugia A. Assessing efficacy and therapeutic claims in emerging indications for recombinant factor VIIa: Regulatory perspectives. <i>Seminars in Hematology</i> 2006;43(1 Suppl 1):S64-S69.	Ineligible study design
FAST: rFVIIa has no effect on death or disability after ICH. <i>Formulary</i> 2007;42:445-446.	Ineligible study design
Felfernig M, Huepfl M. Experience of recombinant activated factor VII (NovoSeven) in the operating theatre and intensive care unit for the management of intracranial bleeding in nonhaemophilic patients. <i>Clinical Neurology & Neurosurgery</i> . 2008;110(3):227-232.	Small sample size
Feng S, Humar A, Pomfret E, et al. Surgical challenges in transplantation: the Fourth Annual American Society of Transplant Surgeons' State-of-the-Art Winter Symposium. <i>Am J Transplant</i> 2005;5(3):428-435.	Ineligible study design
Fenger-Eriksen C, Ingerslev J, Sorensen B. Coagulopathy induced by colloid plasma expanders--search for an efficacious haemostatic intervention. <i>Acta Anaesthesiologica Scandinavica</i> 2006;50(7):899-900.	Ineligible study design
Ferro JM. Update on intracerebral haemorrhage. <i>Journal of Neurology</i> 2006;253(8):985-999.	Ineligible study design
Fetouh FA, Salah M, Sedeek K, et al. 471974 - the efficacy of low dose recombinant factor VIIa in the prophylaxis of bleeding during orthotopic liver transplantation. <i>Canadian Journal of Anaesthesia</i> 2008;55 Suppl 1:471974.	Ineligible study design
Fewel ME, Park P. The emerging role of recombinant-activated factor VII in neurocritical care. <i>Neurocritical Care</i> . 2004;1(1):19-29.	Ineligible study design
Filan PM, Mills JF, Clarnette TD, et al. Spontaneous liver hemorrhage during laparotomy for necrotizing enterocolitis: a potential role for recombinant factor VIIa. <i>J Pediatr</i> 2005;147(6):857-859.	Ineligible study design
Firozvi K, Acs P, Baidas S, et al. Efficacious and safe use of recombinant activated factor VII (rFVIIa) in patients with enoxaparin (ENOX)-induced bleeding and pre-existing hypercoagulable states. <i>Blood</i> 2004;104(11 Part 1):300A.	Ineligible study design
Firozvi K, Deveras RAE, Kessler CM. Reversal of low-molecular-weight heparin-induced bleeding in patients with pre-existing hypercoagulable states with human recombinant activated factor VII concentrate. <i>American Journal of Hematology</i> 2006;81(8):582-589.	Ineligible study design
First Reports of Adverse Drug Reactions in Recent Weeks. <i>Drugs & Therapy Perspectives</i> 2005;21(5):18-20.	Not on rFVIIa
Fischer D, Schloesser R, Buxmann H, et al. Recombinant activated Factor VII as a hemostatic agent in very low birth weight preterms with gastrointestinal hemorrhage and disseminated intravascular coagulation. <i>Journal of Pediatric Hematology/Oncology</i> 2008;30(5):337-342.	Ineligible study design
Fishman PE, Drumheller BC, Dubon ME, et al. Recombinant activated factor VII use in the emergency department. <i>Emergency Medicine Journal</i> 2008;25(10):625-630.	Ineligible study design
Flood VH, Galderisi FC, Lowas SR, et al. Hemorrhagic disease of the newborn despite vitamin K prophylaxis at birth. <i>Pediatric Blood & Cancer</i> 2008;50(5):1075-1077.	Small sample size
Flynn JD, Camp Jr PC, Jahania MS, et al. Successful treatment of refractory bleeding after bridging from acute to chronic left ventricular assist device support with recombinant activated factor VII. <i>ASAIO Journal</i> 2004;50(5):519-521.	Small sample size
Flynn JD, Pajoumand M, Camp Jr PC, et al. Recombinant factor VIIa for refractory bleeding following orthotopic heart transplantation. <i>Annals of Pharmacotherapy</i> 2004;38(10):1639-1642.	Small sample size
Fontaine MJ, Lazarchick J, Taylor S, et al. Perinatal/neonatal case presentation. <i>Journal of Perinatology</i> 2004;24:310-311.	Ineligible study design
Foot CL, Fraser JF, Mullany DV. Common complications after cardiac surgery in the adult: anecdotes, biases... and some evidence. <i>Current Anaesthesia & Critical Care</i> 2005;16:331-345.	Ineligible study design
Fox CJ, Gillespie DL, Cox ED, et al. Damage control resuscitation for vascular surgery in a Combat Support Hospital. <i>Journal of Trauma Injury Infection and Critical Care</i> 2008;65(1):1-9.	Small sample size

Excluded article	Reason for exclusion
Fox CJ, Gillespie DL, Cox ED, et al. The effectiveness of a damage control resuscitation strategy for vascular injury in a combat support hospital: results of a case control study. <i>Journal of Trauma-Injury Infection & Critical Care</i> 2008;64(2 Suppl):S99-S106; discussion S106-S107.	No usable data
Franchini M, Franchi M, Bergamini V, et al. A critical review on the use of recombinant factor VIIa in life-threatening obstetric postpartum hemorrhage. <i>Seminars in Thrombosis & Hemostasis</i> 2008;34(1):104-112.	Ineligible study design
Franchini M, Franchi M, Bergamini V, et al. A critical review on the use of recombinant factor VIIa in life-threatening obstetric postpartum hemorrhage. <i>Seminars in Thrombosis & Hemostasis</i> 2008;34(1):104-112.	Ineligible study design
Franchini M, Lippi G, Franchi M. The use of recombinant activated factor VII in obstetric and gynaecological haemorrhage. <i>BJOG</i> 2007;114(1):8-15.	Ineligible study design
Franchini M, Manzato F, Salvagno GL, et al. Potential role of recombinant activated factor VII for the treatment of severe bleeding associated with disseminated intravascular coagulation: a systematic review. <i>Blood Coagulation & Fibrinolysis</i> 2007;18(7):589-593.	Ineligible study design
Franchini M, Montagnana M, Targher G, et al. The use of recombinant factor VIIa in liver diseases. <i>Blood Coagulation & Fibrinolysis</i> 2008;19(5):341-348.	Ineligible study design
Franchini M, Veneri D, Lippi G. The potential role of recombinant activated FVII in the management of critical hemato-oncological bleeding: a systematic review. <i>Bone Marrow Transplantation</i> 2007;39(12):729-735.	Ineligible study design
Franchini M, Zaffanello M, Veneri D. Recombinant factor VIIa - An update on its clinical use. <i>Thrombosis and Haemostasis</i> 2005;93(6):1027-1035.	Ineligible study design
Franchini M, Zaffanello M, Veneri D. Recombinant factor VIIa. An update on its clinical use. <i>Thromb Haemost</i> 2005;93(6):1027-1035.	Ineligible study design
Franchini M. Recombinant factor VIIa: A review on its clinical use. <i>International Journal of Hematology</i> 2006;83(2):126-138.	Ineligible study design
Franczuk B, Derlatka E, Freedland Y. The effect of recombinant factor VIIa (NovoSeven(R)) on peri-operative bleeding during total knee replacement in a non-hemophiliac patient. <i>Ortopedia Traumatologia Rehabilitacja</i> 2004;6(4):483-489.	Ineligible study design
Fraser IS, Porte RJ, Kouides PA, et al. A benefit-risk review of systemic haemostatic agents - Part 1: In major surgery. <i>Drug Safety</i> 2008;31(3):217-230.	Ineligible study design
Fraser IS, Porte RJ, Kouides PA, et al. A benefit-risk review of systemic haemostatic agents: part 1: in major surgery. <i>Drug Safety</i> 2008;31(3):217-230.	Ineligible study design
Freeman WD, Aguilar MI. Management of warfarin-related intracerebral hemorrhage. <i>Expert Rev Neurother</i> 2008;8(2):271-290.	Ineligible study design
Freeman WD, Brott TG, Barrett KM, et al. Recombinant factor VIIa for rapid reversal of warfarin anticoagulation in acute intracranial hemorrhage. <i>Mayo Clinic Proceedings</i> 2004;79(12):1495-1500.	Small sample size
Freeman WD, Brott TG. Modern treatment options for intracerebral hemorrhage. <i>Current Treatment Options in Neurology</i> 2006;8(2):145-157.	Ineligible study design
Fridberg MJ, Hedner U, Roberts HR, et al. A study of the pharmacokinetics and safety of recombinant activated factor VII in healthy Caucasian and Japanese subjects. <i>Blood Coagulation & Fibrinolysis</i> 2005;16(4):259-266.	No usable data
Friederich PW, Geerdink MG, Spataro M, et al. The effect of the administration of recombinant activated factor VII (NovoSeven) on perioperative blood loss in patients undergoing transabdominal retropubic prostatectomy: the PROSE study. <i>Blood Coagulation & Fibrinolysis</i> 2000;11 Suppl 1:S129-S132.	Duplicate
Friederich PW, Geerdink MGF, Keller TT, et al. The effect of the administration of recombinant activated factor VII (NovoSeven) on perioperative blood loss in patients undergoing transabdominal retropubic prostatectomy: The prose study. <i>Haemostasis</i> 2000;30(1-2):24-25.	Duplicate
Friederich PW, Geerdink MGF, Keller TT, et al. Novel applications of recombinant factor VIIa: The effect of the administration of recombinant factor VII (NovoSeven) on perioperative blood loss in patients undergoing transabdominal retropubic prostatectomy: The Prose study. <i>Infusionstherapie und Transfusionsmedizin</i> 2001;26:112-113.	Duplicate
Friederich PW, Henny Ch P, Messelink EJ, et al. Reduction of perioperative blood loss and transfusion requirement in patients undergoing transabdominal retropubic prostatectomy by administration of recombinant activated factor VII. <i>The Netherlands Journal of Medicine</i> 2001;58.	Duplicate

Excluded article	Reason for exclusion
Friedrich JO. Recombinant activated factor VII for acute intracerebral hemorrhage. <i>N Engl J Med</i> 2005;352(20):2133-2134; author reply 2133-2134.	Ineligible study design
Fu E. Society of Neurosurgical Anesthesia and Critical Care 33rd Annual Scientific Meeting. <i>J Neurosurg Anesthesiol</i> 2006;18:159-160.	Ineligible study design
Gabriel DA, Carr M, Roberts HR. Monitoring coagulation and the clinical effects of recombinant factor VIIa. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):20-24.	Animal or in-vitro study
Gala B, Quintela J, Aguirrezabalaga J, et al. Benefits of recombinant activated factor VII in complicated liver transplantation. <i>Transplant Proc</i> 2005;37(9):3919-3921.	Small sample size
Galan AM, Tonda R, Pino M, et al. Recombinant factor VIIa (rFVIIa) improves hemostasis in patients with chronic liver cirrhosis: Experience from perfusion models with human flowing blood. <i>Hepatology</i> 2001;34(4 Pt 2):531A.	Animal or in-vitro study
Gallipoli P, Robertson M, Tait RC. Off-label use of rFVIIa and its clinical effectiveness: results from a Scottish national audit. <i>British Journal of Haematology</i> 2007;137(Suppl 1):85.	Ineligible study design
Galvan DA, Fink MP. Recombinant factor VIIa in severe trauma: further study needed. <i>Critical Care</i> 2006;10(3):412-413.	Ineligible study design
Gandhimathi K, McLornan D, O'Neill F. Hepatic capsule hemorrhage due to HELLP syndrome managed with recombinant factor VIIa. <i>clinical intensive care</i> . 2004;15(1):15-18.	Ineligible study design
Ganguly S, Spengel K, Tillzer L, et al. Recombinant factor VIIa: increased mortality with unregulated continuous use in bleeding and coagulopathic patients. <i>Vox Sanguinis</i> 2005;89(Suppl 1):15.	Data combined for multiple conditions
Ganguly S, Spengel K, Tilzer LL, et al. Recombinant factor VIIa: unregulated continuous use in patients with bleeding and coagulopathy does not alter mortality and outcome. <i>Clinical & Laboratory Haematology</i> 2006;28(5):309-312.	Data combined for multiple conditions
Ganguly S, Spengel K, Tilzer LL, et al. Recombinant factor VIIa: unregulated continuous use in patients with bleeding and coagulopathy does not alter mortality and outcome. <i>Clinical & Laboratory Haematology</i> 28(5):309-312.	Data combined for multiple conditions
Garcia CJJ, Ventura ML, Lobato PJ, et al. Evaluation of rFVIIa in off-label prescribing. <i>Atencion Farmaceutica</i> 2007;9(3):200-205.	Foreign language
Geeraedts Jr LMG, Kamphuisen PW, Kaasjager HAH, et al. The role of recombinant factor VIIa in the treatment of life-threatening haemorrhage in blunt trauma. <i>Injury</i> 2005;36(4):495-500.	Small sample size
Geisler JP, Linnemeier GC, Manahan KJ. Recombinant factor VIIa to treat late radiation-induced hemorrhagic cystitis - A case report. <i>Journal of Reproductive Medicine</i> 2008;53(5):360-362.	Ineligible study design
Geoghegan J, Tasker L. A response to 'the use of recombinant activated factor VII in the control of haemorrhage following blunt pelvic trauma [comment]'. <i>Anaesthesia</i> 2005;60(11):1156-1157; author reply 1157.	Ineligible study design
Gerald AG. Update on hemostasis: neurosurgery. <i>Surgery</i> 2007;142(4 Suppl):S55-S60.	Ineligible study design
Gerlach R, Marquardt G, Wissing H, et al. Application of recombinant activated factor VII during surgery for a giant skull base hemangiopericytoma to achieve safe hemostasis. Case report. <i>J Neurosurg</i> 2002;96(5):946-948.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Gerotziafas GT, Zervas C, Gavrielidis G, et al. Effective hemostasis with rFVIIa treatment in two patients with severe thrombocytopenia and life-threatening hemorrhage. <i>Am J Hematol</i> 2002;69(3):219-222.	Ineligible study design
Ghavamzadeh A, Alimoghaddam K, Ghaffari H, et al. Treatment of new cases of acute promyelocytic leukaemia by arsenic trioxide. <i>Blood</i> 2004;104(11 Part 1):116A.	Not on rFVIIa
Ghorashian S, Hunt BJ. "Off-license" use of recombinant activated factor VII. <i>Blood Reviews</i> 2004;18(4):245-259.	Ineligible study design
Gibbs NM. The place of recombinant activated factor VII in liver transplantation. <i>Int Anesthesiol Clin</i> 2006;44(3):99-110.	Ineligible study design
Gidiri M, Noble W, Rafique Z, et al. Caesarean section for placenta praevia complicated by postpartum haemorrhage managed successfully with recombinant activated human coagulation Factor VIIa. <i>J Obstet Gynaecol</i> 2004;24(8):925-926.	Ineligible study design
Gielen-Wijffels SE, van Mook WN, van der Geest S, et al. Successful treatment of severe bleeding with recombinant factor VIIa after kidney transplantation. <i>Intensive Care Med</i> 2004;30(6):1232-1234.	Ineligible study design

Excluded article	Reason for exclusion
Gill R, Herbertson M. Recombinant Factor VIIa: A Universal Haemostatic Agent? <i>Annals of Cardiac Anaesthesia</i> 2006;9(2):97-99.	Ineligible study design
Girardis M, Marietta M, Busani S, et al. Rectal amputation sparing by haemostatic therapy with recombinant factor VIIa in a patient with cytomegalovirus-related colitis. <i>Thromb Haemost</i> 2006;95(3):579-580.	Ineligible study design
Girisch M, Rauch R, Carbon R, et al. Refractory bleeding following major surgery of a giant sacrococcygeal teratoma in a premature infant: Successful use of recombinant factor VIIa. <i>European Journal of Pediatrics</i> 2004;163(2):118-119.	Ineligible study design
Girona E, Borrás-Blasco J, Conesa-García V, et al. Successful treatment of severe gastrointestinal bleeding secondary to Crohn disease with recombinant factor VIIa. <i>Southern Medical Journal</i> 2007;100(6):601-604.	Ineligible study design
Gloster E, Ilario M, De Luna J, et al. Off-label use of recombinant activated factor VII (rFVIIa) for bleeding following a percutaneous liver biopsy. <i>Vox Sanguinis</i> 2002;83(Suppl 2):58-59.	Ineligible study design
Gloster E, O'Neill P, DiMaio T, et al. Off-label use of recombinant activated factor VII (rFVIIa) for massive bleeding in trauma and surgery. <i>Vox Sanguinis</i> 2002;83(Suppl 2):59.	Small sample size
Gloster E, Strauss R, DaCosta M, et al. Off-label use of recombinant factor VIIa (rFVIIa) for postoperative hematuria in a factor VII deficient renal transplant patient. <i>Blood</i> 2000;96(11 Part 2):82b-83b.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Goldenberg NA, Manco-Johnson MJ. Pediatric hemostasis and use of plasma components. <i>Best Pract Res Clin Haematol</i> 2006;19(1):143-155.	Ineligible study design
Goldstein JN, Fazen LE, Wendell L, et al. Hyperglycemia on presentation is an independent predictor of thromboembolic events following acute intracerebral hemorrhage. <i>Neurology</i> 2007;68(12 Suppl 1):A336.	No usable data
Goldstein JN, Greenberg SM, Rosand J. Emergency management of intracerebral hemorrhage. <i>Continuum</i> 2006;12(1):13-29.	Ineligible study design
Gong ZY, Gao CQ, Xiao CS, et al. [The use of recombinant activated factor VII for blood loss after cardiovascular surgery]. <i>Chung-Hua Wai Ko Tsa Chih [Chinese Journal of Surgery]</i> 2008;46(19):1497-1501.	Foreign language
Gonzalez Castro A, Suberviola Canas B, Minambres E, et al. [Recombinant factor VIIa (rFVIIa). Description of use in a cohort of critical patients and prognostic markers]. <i>Med Intensiva</i> 2007;31(5):215-219.	Foreign language
Goodnough LT, Hewitt PE, Silliman CC. Joint ASH and AABB educational session. <i>Hematology</i> 2004:457-472.	Ineligible study design
Goodnough LT, Lublin DM, Zhang L, et al. Transfusion medicine service policies for recombinant factor VIIa administration. <i>Transfusion</i> 2004;44(9):1325-1331.	Ineligible study design
Goodnough LT, Shander AS. Recombinant factor VIIa: safety and efficacy. <i>Curr Opin Hematol</i> 2007;14(5):504-509.	Ineligible study design
Goodnough LT. Experiences with recombinant human factor VIIa in patients with thrombocytopenia. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):25-29.	Ineligible study design
Goodnough LT. Treatment of critical bleeding in the future intensive care unit. <i>Intensive Care Medicine</i> 2002;28 Suppl 2:S221.	Ineligible study design
Gordon WC, Clark AD, Walker ID, et al. The role of recombinant factor VIIa in the management of severe haemorrhage requiring massive blood transfusion. <i>British Journal of Haematology</i> 2003;121(Suppl 1):18.	Small sample size
Gowers CJD, Parr MJA. Recombinant activated factor VIIa use in massive transfusion and coagulopathy unresponsive to conventional therapy.[see comment]. <i>Anaesthesia & Intensive Care</i> 2005;33(2):196-200.	Small sample size
Grabowski EF, Bussel JB. Pediatric experience with fondaparinux in deep venous thrombosis. <i>Blood</i> 2006;108(11 Part 1):274A-275A.	Not on rFVIIa
Grant GA. Neurosurgery. <i>Journal of Trauma Injury Infection and Critical Care</i> 2007;62(6 Suppl S):S100-S101.	Ineligible study design
Grant GA. Update on hemostasis: neurosurgery. <i>Surgery (St Louis)</i> 2007;142(4 Suppl S):S55-S60.	Ineligible study design
Greaves P, Madhani M, Hallam S, et al. Off-license use of recombinant factor VIIa: a single centre experience. <i>British Journal of Haematology</i> 2009;145(Suppl 1):34.	Ineligible study design
Green D. Management of bleeding complications of hematologic malignancies. <i>Seminars in Thrombosis and Hemostasis</i> 2007;33(4):427-434.	Ineligible study design

Excluded article	Reason for exclusion
Greenberg SM. Is "compassionate use" compassionate?: rFVIIa for intracerebral hemorrhage [comment]. <i>Neurology</i> 2006;67(6):934-935.	Ineligible study design
Greisen G, Andreasen RB. Recombinant factor VIIa in preterm neonates with prolonged prothrombin time. <i>Blood Coagulation & Fibrinolysis</i> 2003;14(1):117-120.	Other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)
Grintescu I, Tulbure D, Mirea L. [Activated recombinant factor VII (Novoseven) in multiple trauma patients: an outcome analysis]. <i>Chirurgia (Bucuresti)</i> 2006;101(6):615-624.	Foreign language
Grizelj R, Vukovic J, Filipovic-Grcic B, et al. Successful use of recombinant activated FVII and aminocaproic acid in four neonates with life-threatening hemorrhage. <i>Blood Coagulation & Fibrinolysis</i> 2006;17(5):413-415.	Small sample size
Groenland THN, Porte RJ, Metselaar HJ. Liver transplantation and risk of bleeding. <i>Curr Opin Organ Transplant</i> 2007;12:287-293.	Ineligible study design
Groeper KL, Berkenbosch JW, Johnson JO, et al. Recombinant factor VIIa to treat coagulation disturbance, unresponsive to conventional therapy, in the pediatric ICU population. <i>Anesthesiology Abstracts of Scientific Papers Annual Meeting 2002:Abstract No. A-1234.</i>	Ineligible study design
Grotta JC. Management of Primary Hypertensive Hemorrhage of the Brain. <i>Curr Treat Options Neurol</i> 2004;6(6):435-442.	Ineligible study design
Grounds M. Recombinant factor VIIa (rFVIIa) and its use in severe bleeding in surgery and trauma: a review. <i>Blood Reviews</i> 2003;17 Suppl 1:S11-S21.	Ineligible study design
Grounds RM, Bolan C. Clinical experiences and current evidence for therapeutic recombinant factor VIIa treatment in nontrauma settings [erratum appears in <i>Crit Care</i> 2005;9(6):560]. <i>Critical Care (London, England)</i> 2005;9 Suppl 5:S29-S36.	Ineligible study design
Grounds RM, Seebach C, Knothe C, et al. Use of recombinant activated factor VII (Novoseven) in trauma and surgery: analysis of outcomes reported to an international registry. <i>J Intensive Care Med</i> 2006;21(1):27-39.	Duplicate
Grove GH. Recombinant blood components: clinical administration today and tomorrow. <i>World Journal of Surgery</i> 1996;20(9):1194-1199.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Gunduz E, Akay OM, Teke HU, et al. Safety and efficacy of activated recombinant FVII in uncontrolled bleeding episodes. <i>Blood</i> 2006;108(11 Part 2):99B.	Ineligible study design
Gunn KN. Ts12 combating coagulopathy. <i>ANZ Journal of Surgery</i> 2007;77 Suppl 1:A95.	Ineligible study design
Gupta S, Gupta A, Jain A, et al. Outcome of recombinant factor VIIa use for alveolar hemorrhage in hematopoietic stem cell transplant recipients. <i>Blood</i> 2006;108(11 Part 2):77B.	Duplicate
Guyot E, Carillion A, Poli-Merol ML, et al. Use of rFVIIa in two children presenting major bleeding not controlled by the usual treatments before emergent surgery. <i>Paediatr Anaesth</i> 2008;18(12):1226-1228.	Ineligible study design
Haan J, Scalea T. A Jehovah's Witness with complex abdominal trauma and coagulopathy: use of factor VII and a review of the literature. <i>American Surgeon</i> 2005;71(5):414-415.	Small sample size
Haas T, Innerhofer P, Kuhbacher G, et al. Successful reversal of deleterious coagulopathy by recombinant factor VIIa. <i>Anesth Analg</i> 2005;100(1):54-58.	Small sample size
Haenggi D, Steiger HJ. Spontaneous intracerebral haemorrhage in adults: a literature overview. <i>Acta Neurochirurgica</i> 2008;150(4):371-379.	Ineligible study design
Halkos ME, Levy JH, Chen E, et al. Early experience with activated recombinant factor VII for intractable hemorrhage after cardiovascular surgery. <i>Ann Thorac Surg</i> 2005;79(4):1303-1306.	Small sample size
Hall CE, Grotta JC. New era for management of primary hypertensive intracerebral hemorrhage. <i>Current Neurology & Neuroscience Reports</i> 2005;5(1):29-35.	Ineligible study design
Hall K, Forrest P, Sawyer C. The effects of acidosis and hypothermia on blood transfusion requirements following factor VII administration. <i>Anaesth Intensive Care</i> 2007;35(4):494-497.	Data combined for multiple conditions
Hammer GB, Williams GD. Use of recombinant activated factor VII in children. <i>Paediatr Anaesth</i> 2007;17(12):1123-1125.	Ineligible study design

Excluded article	Reason for exclusion
Hanggi D, Steiger HJ. Spontaneous intracerebral haemorrhage in adults: a literature overview. <i>Acta Neurochirurgica</i> 2008;150(4):371-379; discussion 379.	Ineligible study design
Hanley D. Expansion in intracerebral hematoma. <i>Neurocrit Care</i> 2004;1(1):3-4.	Ineligible study design
Hanley JP. Warfarin reversal. <i>Journal of Clinical Pathology</i> 2004;57(11):1132-1139.	Ineligible study design
Hanna WT. Recombinant activated factor VII (rFVIIa)-mediated normalization of INR levels post-coumadin overdose. <i>Blood</i> 2005;106(11 Part 2):106B.	Ineligible study design
Hansen TW. Prophylaxis of intraventricular hemorrhage in premature infants: new potential tools, new potential challenges. <i>Pediatr Crit Care Med</i> 2006;7(1):90-92.	Ineligible study design
Hardy JF, Belisle S, Van der Linden P, et al. Efficacy and safety of activated recombinant factor VII in cardiac surgical patients. <i>Current Opinion in Anaesthesiology</i> 2009;22(1):95-99.	Ineligible study design
Hardy JF, de Moerloose P, Samama CM. The coagulopathy of massive transfusion. <i>Vox Sanguinis</i> 2005;89(3):123-127.	Ineligible study design
Hardy J-F. Managing uncontrolled hemorrhage in trauma and surgery: a novel and promising approach. <i>Canadian Journal of Anaesthesia</i> 2002;49(10):S4-S6.	Ineligible study design
Harkensee C, Vasdev N, Gennery AR, et al. Prevention and management of BK-virus associated haemorrhagic cystitis in children following haematopoietic stem cell transplantation--a systematic review and evidence-based guidance for clinical management. <i>British Journal of Haematology</i> 2008;142(5):717-731.	Ineligible study design
Hart RG, Aguilar MI. Anticoagulation in atrial fibrillation: selected controversies including optimal anticoagulation intensity, treatment of intracerebral hemorrhage. <i>J Thromb Thrombolysis</i> 2008;25(1):26-32.	Ineligible study design
Hartmann M, Sucker C, Boehm O, et al. Effects of cardiac surgery on hemostasis. <i>Transfusion Medicine Reviews</i> 2006;20(3):230-241.	Ineligible study design
Hartmann M, Sucker C, Messing M. Recombinant activated factor VII in the treatment of near-fatal bleeding during pediatric brain tumor surgery. Report of two cases and review of the literature. <i>J Neurosurg</i> 2006;104(1 Suppl):55-58.	Ineligible study design
Hartmann M, Sucker C. Pharmacology and clinical use of recombinant activated factor seven in neurosciences. <i>Neurocritical Care</i> 2007;6(2):149-157.	Ineligible study design
Harvey J, Dardik H, Impeduglia T, et al. Endovascular management of hepatic artery pseudoaneurysm hemorrhage complicating pancreaticoduodenectomy. <i>J Vasc Surg</i> 2006;43(3):613-617.	Ineligible study design
Hasper D, Storm C, Seehofer D, et al. Both sides of the story - cerebral infarction after intra-abdominal bleeding. <i>Intensive Care Med</i> 2006;32(2):340-341.	Ineligible study design
Hatzipantelis ES, Gombakis N, Sidi V, et al. Successful outcome of DIC and life-threatening bleeding in a toddler with neuroblastoma treated with recombinant activated factor VII. <i>Internal & Emergency Medicine</i> 2008;3(2):171-173.	Ineligible study design
Hawryluk GW, Cusimano MD. The role of recombinant activated factor VII in neurosurgery: hope or hype? <i>J Neurosurg</i> 2006;105(6):859-868.	Ineligible study design
Hay CRM. Thrombosis and recombinant factor VIIa [comment]. <i>Journal of Thrombosis & Haemostasis</i> 2004;2(10):1698-1699.	Ineligible study design
Hayward CP, Cina CS, Staunton M, et al. Bleeding and thrombotic problems in a patient with alpha2 plasmin inhibitor deficiency. <i>J Thromb Haemost</i> 2005;3(2):399-401.	Ineligible study design
Hearnshaw S, Travis S, Murphy M. The role of blood transfusion in the management of upper and lower intestinal tract bleeding. <i>Best Practice & Research in Clinical Gastroenterology</i> 2008;22(2):355-371.	Ineligible study design
Hebert P. Treatment of severe coagulopathy after gunshot injury to the head using recombinant activated factor VII: commentary. <i>J Crit Care</i> 2005;20(2):180.	Ineligible study design
Hedner U, Brun NC. Recombinant factor VIIa (rFVIIa): its potential role as a hemostatic agent. <i>Neuroradiology</i> 2007;49(10):789-793.	Ineligible study design
Hedner U, Erhardtsen E. Potential role for rFVIIa in transfusion medicine. <i>Transfusion</i> 2002;42(1):114-124.	Ineligible study design
Hedner U, Erhardtsen E. Potential role of recombinant factor VIIa as a hemostatic agent. <i>Clinical Advances in Hematology & Oncology</i> 2003;1(2):112-119.	Ineligible study design
Hedner U, Ingerslev J. Clinical use of recombinant FVIIa (rFVIIa). <i>Transfus Sci</i> 1998;19(2):163-176.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)

Excluded article	Reason for exclusion
Hedner U, Lund-Hansen T, Heikoop JC, et al Coagulation factor VII and follicle stimulating hormone. Made by genetic engineering (No. 8 in a series of articles to promote a better understanding of the use of genetic engineering). <i>Journal of Biotechnology</i> 1998;61(3):231-236.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Hedner U. Dosing with recombinant factor viia based on current evidence. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):35-39.	Ineligible study design
Hedner U. Factor VIIa and its potential therapeutic use in bleeding-associated pathologies. <i>Thrombosis and Haemostasis</i> 2008;100(4):557-562.	Ineligible study design
Hedner U. General haemostatic agents--fact or fiction? <i>Pathophysiology of Haemostasis & Thrombosis</i> 2002;32 Suppl 1:33-36.	Ineligible study design
Hedner U. Mechanism of action and clinical experience of rFVIIa. <i>Journal of Biotechnology</i> 2005;118(Suppl 1):S63-S64.	Ineligible study design
Hedner U. Mechanism of action of factor VIIa in the treatment of coagulopathies. <i>Semin Thromb Hemost</i> 2006;32 Suppl 1:77-85.	Ineligible study design
Hedner U. Mechanism of action of recombinant activated factor VII: An update. <i>Seminars in Hematology</i> 2006;43(1 Suppl. 1):S105-S107.	Ineligible study design
Hedner U. Mechanism of action, development and clinical experience of recombinant FVIIa. <i>Journal of Biotechnology</i> 2006;124(4):747-757.	Ineligible study design
Hedner U. NOVOSEVEN (recombinant FVIIa) in bleeding disorders. <i>Vox Sanguinis</i> 1996;70(Suppl 2):52.	Unable to obtain publication
Hedner U. NovoSeven as a universal haemostatic agent. <i>Blood Coagul Fibrinolysis</i> 2000;11 Suppl 1:S107-S111.	Ineligible study design
Hedner U. NovoSeven(R) as a universal haemostatic agent. <i>Blood Coagulation and Fibrinolysis</i> . 2000;11(Suppl 1):S107-S111.	Ineligible study design
Hedner U. Recombinant activated factor VII as a universal haemostatic agent. <i>Blood Coagul Fibrinolysis</i> 1998;9 Suppl 1:S147-S152.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Hedner U. Recombinant factor VIIa (NovoSeven(R)) as a hemostatic agent. <i>Seminars in Hematology</i> 2001;38(4 Suppl 12):43-47.	Ineligible study design
Hedner U. Recombinant FVIIa. <i>Vox Sanguinis</i> 2004;87(Suppl 2):25-28.	Ineligible study design
Hedner U. Single-dose administration of factor VIIa. <i>Novo Nordisk HealthCare AG</i> 2008.	Ineligible study design
Heegaard W, Biros M. Traumatic brain injury. <i>Emergency Medicine Clinics of North America</i> 25(3):655-678.	Ineligible study design
Heier HE, Bugge W, Hjelmeland K, et al. Transfusion vs. alternative treatment modalities in acute bleeding: a systematic review [see comment]. <i>Acta Anaesthesiologica Scandinavica</i> 2006;50(8):920-931.	Ineligible study design
Heier HE. Evidence-based transfusion medicine. <i>Vox Sanguinis</i> 2005;89(Suppl 1):118.	Ineligible study design
Hein OV, von Heymann C, Morgera S, et al. Protracted bleeding after hirudin anticoagulation for cardiac surgery in a patient with HIT II and chronic renal failure. <i>Artificial Organs</i> 2005;29(6):507-510.	Small sample size
Heise D, Brauer A, Quintel M. Recombinant activated factor VII (Novo7(R)) in patients with ventricular assist devices: Case report and review of the current literature. <i>Journal Of Cardiothoracic Surgery</i> 2007;2:47.	Small sample size
Heisel M, Nagib M, Madsen L, et al. Brief report - use of recombinant factor VIIa (rFVIIa) to control intraoperative bleeding in pediatric brain tumor patients. <i>Pediatric Blood & Cancer</i> 2004;43(6):703-705.	Ineligible study design
Heisel M, Nagib M, Madsen L, et al. The use of recombinant factor VIIa (rFVIIa) to control intraoperative bleeding in pediatric brain Tumor patients. <i>Blood</i> 2002;100(11):Abstract No. 2802.	Ineligible study design
Heisel M, Nagib M, Madsen L, et al. Use of recombinant factor VIIa (rFVIIa) to control intraoperative bleeding in pediatric brain tumor patients. <i>Pediatric Blood & Cancer</i> 2004;43(6):703-705.	Ineligible study design
Helie F, Hardy JF. Anesthesiologists and the pharmaceutical industry: awareness is paramount. <i>Can J Anaesth</i> 2007;54(12):1026-1027; author reply 1027-1028.	Ineligible study design
Helie F, Hardy J-F. Anesthesiologists and the pharmaceutical industry: awareness is paramount. <i>Canadian Journal of Anesthesia</i> 2007;54(12):1026-1027.	Ineligible study design
Heller M, Lau W, Pamino-Canizares J, et al. A comprehensive review of rFVIIa use in a tertiary care pediatric center. <i>Pediatric Blood & Cancer</i> 2008;50(5):1013-1017.	No usable data

Excluded article	Reason for exclusion
Heller M, Lau W, Pazmino-Canizares J, et al. A comprehensive review of rFVIIa use in a tertiary care pediatric center. <i>Pediatric Blood & Cancer</i> 2008;50(5):1013-1017.	No usable data
Hendriks HG, van der Maaten JM, de Wolf J, et al. An effective treatment of severe intractable bleeding after valve repair by one single dose of activated recombinant factor VII. <i>Anesth Analg</i> 2001;93(2):287-289, 2nd contents page.	Small sample size
Hendriks HGD, Meijer K, de Wolf JTM, et al. Effects of recombinant activated factor VII on coagulation measured by thromboelastography in liver transplantation. <i>Blood Coagulation & Fibrinolysis</i> 2002;13(4):309-313.	Small sample size
Henrich W, Surbek D, Kainer F, et al. Diagnosis and treatment of peripartum bleeding. <i>Journal of Perinatal Medicine</i> 2008;36(6):467-478.	Ineligible study design
Herbertson M. Recombinant activated factor VII in cardiac surgery. <i>Blood Coagulation & Fibrinolysis</i> 2004;15 Suppl 1:S31-S32.	Duplicate
Hermans CRJR, Deney V. Rebuttal: accidental overdosage of recombinant factor VIIa due to mistaken package size: an inappropriate case report [comment]. <i>Thrombosis & Haemostasis</i> 2004;92(6):1455-1456; author reply 1456.	Ineligible study design
Hers I, Mumford A. Understanding the therapeutic action of recombinant factor VIIa in platelet disorders. <i>Platelets (Abingdon)</i> . 2008;19(8):571-581.	Ineligible study design
Heslet L, Nielsen JD, Levi M, et al. Successful pulmonary administration of activated recombinant factor VII in diffuse alveolar hemorrhage. <i>Critical Care (London, England)</i> 2006;10(6):R177.	Ineligible study design
Hess JR, Zimrin AB. Massive blood transfusion for trauma. <i>Current Opinion in Hematology</i> 2005;12(6):488-492.	Ineligible study design
Heuer L, Blumenberg D. Accidental overdosage of recombinant factor VIIa due to mistaken package size. <i>Thrombosis and Haemostasis</i> 2004;91(6):1249-1250.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Heuer L, Blumenberg D. Management of bleeding in a multi-transfused patient with positive HLA class I alloantibodies and thrombocytopenia associated with platelet dysfunction refractory to transfusion of cross-matched platelets. <i>Blood Coagulation & Fibrinolysis</i> 2005;16(4):287-290.	Ineligible study design
Heuer L, Mathias D, Mathine K, et al. Recombinant Factor VIIa [rFVIIa - NovoSeven(R)] for Diffuse Intractable Bleedings. <i>Anesthesiology Abstracts of Scientific Papers Annual Meeting 2002:Abstract No. A-391</i> .	Small sample size
Heymann Cv, Kastrup M, Redlich U, et al. Experiences with recombinant activated factor VII (rFVIIa) for refractory bleeding after cardiac surgery - a retrospective analysis. <i>Anesthesiology Abstracts of Scientific Papers Annual Meeting 2003:Abstract No. A-442</i> .	Other: unpublished data
Hicks K, Peng D, Gajewski JL. Treatment of diffuse alveolar hemorrhage after allogeneic bone marrow transplant with recombinant factor VIIa. <i>Bone Marrow Transplant</i> 2002;30(12):975-978.	Ineligible study design
Higgins PDR, Fontana RJ. Liver transplantation in acute liver failure. <i>Panminerva Medica</i> 2003;45(2):85-94.	Ineligible study design
Hill JD, Reinhartz O. Clinical outcomes in pediatric patients implanted with Thoratec ventricular assist device. <i>Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu</i> 2006:115-122.	No usable data
Ho AMH, Dion PW, Karmakar MK. Use of recombinant activated factor VII in patients with severe coagulopathy and bleeding [comment]. <i>Anesthesiology</i> 2003;98(4):1025-1026; author reply 1026-1027.	Ineligible study design
Hoffman M, Hoffman M. FVIIa: you've come a long way, baby [comment]. <i>Blood</i> 2008;112(8):3002-3003.	Animal or in-vitro study
Hoffman M, Monroe DM, Hoffman M, et al. Tissue factor in brain is not saturated with factor VIIa: implications for factor VIIa dosing in intracerebral hemorrhage. <i>Stroke</i> 2009;40(8):2882-2884	Animal or in-vitro study
Hoffman M, Monroe DM, Roberts HR. Platelet-dependent action of high-dose factor VIIa. <i>Blood</i> 2002;100(1):364-365; author reply 365.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Hoffman M. A cell-based model of coagulation and the role of factor VIIa. <i>Blood Rev</i> 2003;17 Suppl 1:S1-S5.	Animal or in-vitro study
Hoffman M. Laboratory monitoring of high-dose factor VIIa therapy [comment]. <i>Annals of Internal Medicine</i> 2003;139(9):791.	Ineligible study design

Excluded article	Reason for exclusion
Hoffman R, Mahajana A, Agmon P, et al. Successful use of recombinant activated factor VII (Novoseven(R)) in controlling severe intra-abdominal bleeding after liver needle biopsy. <i>Thrombosis and Haemostasis</i> 2002;87(2):346-347.	Ineligible study design
Holcomb JB, Hoots K, Moore FA. Treatment of an acquired coagulopathy with recombinant activated factor VII in a damage-control patient. <i>Military Medicine</i> 2005;170(4):287-290.	Small sample size
Holcomb JB, Neville HL, Fischer CF, et al. Use of recombinant FVIIa for intraperitoneal coagulopathic bleeding in a septic patient. <i>Curr Surg</i> 2003;60(4):423-427.	Ineligible study design
Holcomb JB. Methods for improved hemorrhage control. <i>Critical Care (London, England)</i> 2004;8 Suppl 2:S57-S60.	Ineligible study design
Holcomb JB. Use of recombinant activated factor VII to treat the acquired coagulopathy of trauma. <i>J Trauma</i> 2005;58(6):1298-1303.	Ineligible study design
Hollnberger H, Gruber E, Seelbach-Goebel B. Major post-partum hemorrhage and treatment with recombinant factor VIIa. <i>Anesth Analg</i> 2005;101(6):1886-1887.	Ineligible study design
Hoots WK. Challenges in the therapeutic use of a "so-called" universal hemostatic agent: recombinant factor VIIa. <i>Hematology</i> 2006:426-431.	Ineligible study design
Hoots WK. Hemorrhage following hematopoietic stem cell transplantation--which arrows belong in the quiver? [comment]. <i>Journal of Thrombosis & Haemostasis</i> 2005;3(9):1933-1934.	Ineligible study design
Horton JD, DeZee KJ, Wagner M. Use of rFVIIa in the trauma setting--practice patterns in United States trauma centers. <i>American Surgeon</i> 2008;74(5):413-417.	No usable data
Hossain NH, Farzana TF, Shamsi TS, et al. Use of activated recombinant factor VII for the control of post partum hemorrhage (PTH). <i>Blood</i> 2006;108(11 Part 2):84B-85B.	Ineligible study design
Hoyt DB. A clinical review of bleeding dilemmas in trauma. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):40-43.	Ineligible study design
Hsia CC, Chin-Yee IH, McAlister VC, et al. Use of recombinant activated factor VII in patients without hemophilia: a meta-analysis of randomized control trials. <i>Annals of Surgery</i> 2008;248(1):61-68.	Ineligible study design
Hsia CC, Zurawska JH, Tong MZY, et al. Recombinant activated factor VII (rFVIIa) in the treatment of non-hemophilia patients: Physician underreporting of thromboembolic adverse events. <i>Blood</i> 2007;110(11 Part 1):924A.	Data combined for multiple conditions
Hsieh A, Cheong I. Use of recombinant activated factor VII in a Jehovah's Witness patient. <i>Am J Emerg Med</i> 2007;25(9):1085 e1-2.	Ineligible study design
Hsieh PC, Awad IA, Getch CC, et al. Current updates in perioperative management of intracerebral hemorrhage. <i>Neurol Clin</i> 2006;24(4):745-764.	Ineligible study design
Hu Q, Brady JO. Recombinant activated factor VII for treatment of enoxaparin-induced bleeding. <i>Mayo Clin Proc</i> 2004;79(6):827.	Ineligible study design
Huang WY, Kruskal MS, Bauer KA, et al. The use of recombinant activated factor VII in three patients with central nervous system hemorrhages associated with factor VII deficiency. <i>Transfusion</i> 2004;44(11):1562-1566.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Hubbard D, Tobias JD. Intracerebral hemorrhage due to hemorrhagic disease of the newborn and failure to administer vitamin K at birth [see comment] [summary for patients in <i>South Med J</i> 2006 Nov;99(11):1317; PMID: 17201037]. <i>Southern Medical Journal</i> 2006;99(11):1216-1220.	Small sample size
Hughes DB, Ullery BW, Barie PS. The contemporary approach to the care of Jehovah's Witnesses. <i>Journal of Trauma Injury Infection and Critical Care</i> 2008;65(1):237-247.	Ineligible study design
Hurst T, Blanckley S, Forrest M. Recombinant Factor VIIa in blunt pelvic trauma [comment]. <i>Anaesthesia</i> 2005;60(12):1244-1245; author reply 1245.	Ineligible study design
Huth-Kuehne A, Hampel H. Successful use of recombinant factor VIIA (rFVIIA) in a patient with impaired liver function and bleeding. <i>Journal of Hepatology</i> 1999;30(Suppl 1):200.	Ineligible study design
Huvers F, Slappendel R, Benraad B, et al. Treatment of postoperative bleeding after fondaparinux with rFVIIa and tranexamic acid. <i>Netherlands Journal of Medicine</i> 2005;63(5):184-186.	Ineligible study design
Hyde CJ, Stanworth SJ, Murphy MF. Can you see the wood for the trees? Making sense of forest plots in systematic reviews 2. Analysis of the combined results from the included studies. <i>Transfusion</i> 2008;48(4):580-583.	Not on rFVIIa
Ickx BE. rFVIIa (Novoseven): the new panacea? <i>Acta Anaesthesiologica Belgica</i> 2003;54(4):333-335.	Ineligible study design

Excluded article	Reason for exclusion
Imberti R. Efficacy and safety of factor VIIa on rebleeding after surgery for spontaneous intracerebral hemorrhage (ICH). <i>ClinicalTrials.gov</i> . 2005.	No usable data
Inagaki M, Mori T, Tsunematsu Y, et al. Use of recombinant activated factor VII to control bleeding in a young child with qualitative platelet disorder: a case report. <i>Blood Coagul Fibrinolysis</i> 2006;17(4):317-322.	Other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)
Ingerslev J, Sneppen O, Hvid I, et al. Treatment of acute bleeding episodes with rFVIIa. <i>Vox Sang</i> 1999;77 Suppl 1:42-46.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Ingerslev J, Vanek T, Culic S. Use of recombinant factor VIIa for emergency reversal of anticoagulation [see comment]. <i>Journal of Postgraduate Medicine</i> 2007;53(1):17-22.	Small sample size
Ionita CC, Ferrara J, McDonagh DL, et al. Systemic hemostasis with recombinant-activated factor VII followed by local thrombolysis with recombinant tissue plasminogen activator in intraventricular hemorrhage. <i>Neurocrit Care</i> 2005;3(3):246-248.	Small sample size
Iorio A. Latrogenic causes of an ICH: OAT therapy. <i>European Journal of Anaesthesiology</i> . 2008;25(Suppl 42):8-11.	Ineligible study design
Iorio A. rFVIIa in ICH in patients treated with anticoagulants or anti-platelets. <i>ClinicalTrials.gov</i> . 2005.	No usable data
Ippoliti C, Hey D, Donato ML, et al. Use of activated recombinant factor VII (rFVIIa) for treatment of pulmonary hemorrhage in stem cell transplantation recipients. <i>Blood</i> 2002;100(11):Abstract No. 3308.	Ineligible study design
Isbister J, Phillips L, Dunkley S, et al. Recombinant activated factor VII in critical bleeding: experience from the Australian and New Zealand Haemostasis Register. <i>Intern Med J</i> 2008;38(3):156-165.	Data combined for multiple conditions
Islam J, Azhar S, Alperin JB, et al. Recombinant factor VIIa for uncontrolled bleeding in 2 different cases of coagulopathy. <i>J Am Board Fam Pract</i> 2003;16(6):549-552.	Ineligible study design
Jabbour N, Gagandeep S, Peilin AC, et al. Recombinant human coagulation factor VIIa in Jehovah's Witness patients undergoing liver transplantation. <i>Am Surg</i> . 2005;71(2):175-9.	Small sample size
Jaffe J, Alkhawam L, Du H, et al. Outcome predictors and spectrum of treatment eligibility with prospective protocolized management of intracerebral hemorrhage. <i>Neurosurgery</i> 2009;64(3):436-445.	No usable data
Jaggers J, Lawson JH. Coagulopathy and inflammation in neonatal heart surgery: mechanisms and strategies. <i>Annals of Thoracic Surgery</i> 2006;81(6):S2360-S2366.	Ineligible study design
James KMH, Melikian CN, Chowdary P, et al. Thromboelastography-guided recombinant factor VIIa administration in a patient with refractory autoimmune idiopathic thrombocytopenia. <i>Anesthesia & Analgesia</i> . 2008;107(2):402-405.	Ineligible study design
Jansen JO, Thomas R, Loudon MA, et al. Damage control resuscitation for patients with major trauma. <i>BMJ</i> 2009;338:b1778.	Ineligible study design
Jaschinski U, Ried M, Lichtwarck-Aschoff M, et al. Bleeding diathesis due to failed antagonism of heparin: successful treatment with recombinant factor VIIa. <i>Anesth Analg</i> 2004;99(6):1872.	Small sample size
Jayr C, Kuhlman L, Lodge P, et al. Recombinant factor VIIa in partial hepatectomy: a randomized, placebo-controlled, double-blind clinical trial. <i>Anesthesiology Abstracts of Scientific Papers Annual Meeting 2003:Abstract No. A-151</i> .	Duplicate
Jeffers L, Balart L, Erhardtson E, et al. Efficacy and safety of rFVIIa in patients with severe coagulopathy undergoing laparoscopic liver biopsy. <i>Blood</i> 1999;94(10 Suppl 1 Part 1):236a.	Duplicate
Jeffers LJ, Balart L, Erhardtson E, et al. Novoseven (rFVIIa) in patients with severe coagulopathy undergoing laparoscopic liver biopsy. <i>Hepatology</i> 1999;30(4 Part 2):232A.	Duplicate
Jeffers LJ, Bernstein DE, Erhardtson E, et al. The use of recombinant factor VIIA (rFVIIA) in laparoscopic liver biopsy (LB): A pilot trial. <i>Gastroenterology</i> 1998;114(4 Part 2):A1264-A1265.	Duplicate
Jeffrey GP, McCall J, Gane E, et al. Liver transplantation in Jehovah's Witness patients in Australasia. <i>Med J Aust</i> 2007;187(3):188-189.	Small sample size
Jen H, Shew S, Jen H, et al. Recombinant activated factor VII use in critically ill infants with active hemorrhage. <i>Journal of Pediatric Surgery</i> 2008;43(12):2235-2238.	Ineligible study design

Excluded article	Reason for exclusion
Jha A, Balasubramanian M, Charania R, et al. Treatment of diffuse alveolar hemorrhage with recombinant factor VIIa in patients with hematologic malignancies. <i>Blood</i> 2005;106(11 Part 1):607A.	Ineligible study design
Jimenez-Saenz M. Recombinant factor VIIa for variceal bleeding: when, why, and how? <i>Gastroenterology</i> 2005;128(4):1150-1151; author reply 1151.	Ineligible study design
Jirapinyo M, Manonai J, Herabutya Y, et al. Effectiveness of recombinant activated factor VII (rFVII a) for controlling intractable postpartum bleeding: report of two cases and literature review. <i>J Med Assoc Thai</i> 2007;90(5):977-981.	Ineligible study design
Johannessen M, Nielsen G, Nordfang O. Comparison of the factor VII:C clot analysis and a modified activated factor VII analysis for monitoring factor VII activity in patients treated with recombinant activated factor VII (NovoSeven). <i>Blood Coagul Fibrinolysis</i> 2000;11 Suppl 1:S159-S164.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Johansson PI, Eriksen K, Alsbjorn B. Rescue treatment with recombinant factor VIIa is effective in patients with life-threatening bleedings secondary to major wound excision: a report of four cases. <i>Journal of Trauma-Injury Infection & Critical Care</i> 2006;61(4):1016-1018.	Ineligible study design
Johansson PI. Off-label use of recombinant factor VIIa for treatment of haemorrhage: results from randomized clinical trials. <i>Vox Sang</i> 2008.	Ineligible study design
Johansson PI. Off-label use of recombinant factor VIIa for treatment of haemorrhage: results from randomized clinical trials. <i>Vox Sanguinis</i> 2008;95(1):1-7.	Duplicate
Johnson SJ, Ross MB, Moores KG. Dosing factor VIIa (recombinant) in nonhemophiliac patients with bleeding after cardiac surgery. <i>Am J Health Syst Pharm</i> 2007;64(17):1808-1812.	Ineligible study design
Jureczko L, Kolacz M, Trzebicki J, et al. Perioperative use of recombinant activated factor VII in liver transplantation. <i>Ann Transplant</i> 2003;8(4):40-42.	Small sample size
Jureczko L, Trzebicki J, Zawadzki A, et al. Application of recombinant activated factor VII for treatment of impaired haemostasis during liver transplantation in recipients with Wilson's disease--a report of two cases. <i>Annals of Transplantation</i> 2002;7(3):52-54.	Small sample size
Jurlander B, Thim L, Klausen NK, et al. Recombinant activated factor VII (rFVIIa): characterization, manufacturing, and clinical development. <i>Seminars in Thrombosis & Hemostasis</i> 2001;27(4):373-384.	Ineligible study design
Juvela S, Kase CS. Advances in intracerebral hemorrhage management. <i>Stroke</i> 2006;37(2):301-304.	Ineligible study design
Kabakchieva R, Kenderova V, Perenovska P, et al. Recombinant factor VIIa - NovoSeven in pediatric practice. <i>Acta Physiologica Congress</i> :P1424.	Ineligible study design
Kalainov DM, Valentino LA, Kalainov DM, et al. Recombinant activated factor VII as a temporary reversal agent for warfarin anticoagulation: a cautionary report on an off-label application. <i>American Journal of Orthopedics (Chatham, NJ)</i> 2008;37(11):572-574.	Ineligible study design
Kaleelrahman M, Minford A, Parapia LA. Use of recombinant factor VIIa in inherited platelet disorders [comment]. <i>British Journal of Haematology</i> 2004;125(1):95-96.	Other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)
Kalenka A, Munch E, Fiedler F. Recombinant factor VIIa to treat traumatic bleeding in a children. <i>Paediatric Anaesthesia</i> 2005;15(11):1025-1027.	Small sample size
Kalicenski P, Kaminski A, Drewniak T, et al. Quick correction of hemostasis in two patients with fulminant liver failure undergoing liver transplantation by recombinant activated factor VII. <i>Transplant Proc</i> 1999;31(1-2):378-379.	Small sample size
Kamphuisen PW, van den Akker JM, Kaasjager KA, et al. Control of life-threatening pulmonary bleeding with activated recombinant factor VII. <i>Am J Med</i> 2002;112(4):332-333.	Small sample size
Karadimov D, Binev K, Nachkov Y, et al. Use of activated recombinant Factor VII (NovoSeven) during neurosurgery. <i>Journal of Neurosurgical Anesthesiology</i> 2003;15(4):330-332.	Ineligible study design
Karadimov D, Bochev D, Cherkezev J, et al. Preoperative preparation of patients with liver cirrhosis and massive bleeding from oesophageal varices. <i>Anaesthesiology and Intensive Care</i> 2005;32(1):28-31.	Unable to obtain publication
Karalapillai D, Popham P. Recombinant factor VIIa in massive postpartum haemorrhage. <i>Int J Obstet Anesth</i> 2007;16(1):29-34.	Ineligible study design

Excluded article	Reason for exclusion
Karalapillai D. Audit of factor VIIa for bleeding resistant to conventional therapy following complex cardiac surgery (vol 53, pg 926, 2006). Canadian Journal of Anesthesia 2006;53(12):1271.	Ineligible study design
Karimi M, Zakerinia M, Khojasteh HN, et al. Successful treatment of cyclophosphamide induced intractable hemorrhagic cystitis with recombinant FVIIa (NovoSeven) after allogenic bone marrow transplantation. Journal of Thrombosis & Haemostasis 2004;2(10):1853-1855.	Ineligible study design
Karkouti K, Beattie WS, Crowther MA, et al. The role of recombinant factor VIIa in on-pump cardiac surgery: proceedings of the Canadian Consensus Conference. Can J Anaesth 2007;54(7):573-582.	Ineligible study design
Karkouti K, Wijeyesundera D, McCluskey S, et al. Efficacy and safety of recombinant factor VIIa (rF-VIIa) for treating refractory blood loss after cardiac surgery: an open-label single-arm clinical trial. Anesthesiology Abstracts of Scientific Papers Annual Meeting 2003:Abstract No. A-164.	Duplicate
Karkouti K, Yau TM, Riaz S, et al. Determinants of complications with recombinant factor VIIa for refractory blood loss in cardiac surgery. Canadian Journal of Anaesthesia 2006;53(8):802-809.	Duplicate
Kase CS. Advances in intracerebral haemorrhage management. European Journal of Anaesthesiology - Supplement 2008;42:16-22.	Ineligible study design
Kase CS. Hemostatic treatment in the early stage of intracerebral hemorrhage: the recombinant factor VIIa experience. Stroke 2005;36(10):2321-2322.	Ineligible study design
Kashyap AS, Kashyap S. The clot thickens! In thin air. Arch Intern Med 2002;162(15):1783.	Not on rFVIIa
Kastrup M, von Heymann C, Hotz H, et al. Recombinant factor VIIa after aortic valve replacement in a patient with osteogenesis imperfecta. Ann Thorac Surg 2002;74(3):910-912.	Small sample size
Kaw Jr LL, Coimbra R, Potenza BM, et al. The use of recombinant factor VIIa for severe intractable bleeding during spine surgery. Spine 2004;29(12):1384-1387; discussion 1388.	Small sample size
Kempton CL, Harvey III RD, Roberts HR. Novel therapeutic agents in the management of hemorrhage and thrombosis. Cardiovascular & Hematological Agents in Medicinal Chemistry 2006;4(4):319-334.	Ineligible study design
Kenet G, Walden R, Eldad A, et al. Treatment of traumatic bleeding with recombinant factor VIIa. Lancet 1999;354(9193):1879.	Small sample size
Kenet G. Recombinant FVIIa for profuse bleeding in trauma and surgery. Journal fur Anesthesie und Intesivbehandlung 2001;8(3):112.	Unable to obtain publication
Kessler C, Knudsen JB. Recombinant factor VIIa in patients without congenital coagulation disorders - a new registry on investigational use. Blood 2002;100(11):Abstract No. 4051.	No data reported
Kessler C, Szurlej D, Heymann Cv. Recombinant factor VIIa (rFVIIa) reverses refractory post-operative cardiac bleeding: results from cases reported to the haemostasis.com registry. Blood 2002;100(11):Abstract No. 4050.	Small sample size
Kessler C. Haemorrhagic complications of thrombocytopenia and oral anticoagulation: is there a role for recombinant activated factor VII? Intensive Care Medicine 2002;28 Suppl 2:S228-S234.	Ineligible study design
Kessler C. Haemostasis.com: clinical experiences in the investigational use of rFVIIa in the management of severe haemorrhage. British Journal of Haematology 2004;127(2):230.	Ineligible study design
Kessler CM. Antidotes to haemorrhage: recombinant factor VIIa. Best Pract Res Clin Haematol 2004;17(1):183-197.	Ineligible study design
Kessler CM. Current and future challenges of antithrombotic agents and anticoagulants: Strategies for reversal of hemorrhagic complications. Seminars in Hematology 2004;41(1 Suppl 1):44-50.	Ineligible study design
Kessler CM. New perspectives in hemophilia treatment. Hematology 2005:429-435.	Ineligible study design
Key N. Current insights on the risk of thrombogenicity with off-label use of rFVIIa. Clinical Advances in Hematology & Oncology 2006;4(1):34-35.	Ineligible study design
Key NS, Christie BA, Jones B, et al. Evaluation of the in vivo effect of rFVIIa (Novoseven) using the clot signature analyzer (CSA). Haemostasis 2000;30(Suppl 1):43.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)

Excluded article	Reason for exclusion
Key NS. Recombinant FVIIa for intractable hemorrhage: more questions than answers. <i>Transfusion</i> 2003;43(12):1649-1651.	Ineligible study design
Khan AZ, Parry JM, Crowley WF, et al. Recombinant factor VIIa for the treatment of severe postoperative and traumatic hemorrhage. <i>American Journal of Surgery</i> 2005;189(3):331-334.	Small sample size
Khan ZH, Soltani AE, Rahmani P. Postoperative pulmonary thromboembolism possibly associated with recombinant activated factor VII infusion for the treatment of uncontrolled hemorrhage during vertebral instrumentation. <i>J Anesth</i> 2007;21(2):258-260.	Small sample size
Kim JY, Lee KS, Kwon SH, et al. Successful treatment of intractable gastrointestinal hemorrhage with low dose of recombinant FVIIa (Novoseven (R)) in pediatric patient without coagulation deficiencies. <i>Blood</i> 2004;104(11 Part 2):79B.	Ineligible study design
Kissela BM, Eckman MH. Cost effectiveness of recombinant factor VIIa for treatment of intracerebral hemorrhage. <i>BMC Neurology</i> 2008;8:17.	Ineligible study design
Kjalke M, Ezban M, Hedner U. Increased initial thrombin generation may explain the efficacy of high-dose factor VIIa in thrombocytopenia. <i>Blood</i> 1999;94(10 Suppl 1 Part 1):451a.	Animal or in-vitro study
Klamroth R, Gottstein S, Landgraf H. Successful use of recombinant factor VIIa to prevent bleeding during major surgery in a patient with severe immune thrombocytopenia. <i>Blood</i> 2002;100(11):Abstract No. 3779.	Ineligible study design
Klitgaard T, Nielsen TG. Overview of the human pharmacokinetics of recombinant activated factor VII. <i>British Journal of Clinical Pharmacology</i> 2008;65(1):3-11.	In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
Klitgaard T, Tabanera y Palacios R, Boffard KD, et al. Pharmacokinetics of recombinant activated factor VII in trauma patients with severe bleeding. <i>Critical Care (London, England)</i> 2006;10(4):R104.	In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
Klitgaard T. Application of trial simulation in the design of a clinical study of recombinant factor (rFVIIa) in cirrhotic patients with active varicose bleeding. <i>Clinical Pharmacology & Therapeutics</i> 2004;75(2):P40.	In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
Kluger Y, Riou B, Rossaint R, et al. Safety of rFVIIa in hemodynamically unstable polytrauma patients with traumatic brain injury: post hoc analysis of 30 patients from a prospective, randomized, placebo-controlled, double-blind clinical trial. <i>Critical Care (London, England)</i> 2007;11(4):R85.	Duplicate
Knight M, Ukoss. Peripartum hysterectomy in the UK: management and outcomes of the associated haemorrhage [see comment]. <i>BJOG: An International Journal of Obstetrics & Gynaecology</i> 2007;114(11):1380-1387.	Ineligible study design
Kogan A, Berman M, Kassif Y, et al. Use of recombinant factor VII to control bleeding in a patient supported by right ventricular assist device after heart transplantation. <i>Journal of Heart & Lung Transplantation</i> 2005;24(3):347-349.	Small sample size
Kogan A, Berman M, Stein M, et al. Recombinant factor VIIa use in cardiac surgery--expanding the arsenal therapy for intractable bleeding? <i>Journal of Cardiovascular Surgery</i> 2004;45(6):569-571.	Small sample size
Kogler VM, Slobodnjak Z, Samarzija M, et al. Successful use of activated recombinant factor VII in life-threatening bleeding after thoracic surgery. <i>Swiss Medical Weekly</i> 2007;137(27-28):407-410.	Ineligible study design
Korte WC, Moor S. Near fatal hemorrhage in traumatic bilateral leg amputation with coagulopathy, acidosis, and hypothermia and salvage therapy with recombinant factor VIIa. <i>Journal of Trauma-Injury Infection & Critical Care</i> 2007;63(1):E1-E4.	Small sample size
Kositchaiwat C, Chuansumrit A. Experiences with recombinant factor VIIa for the prevention of bleeding in patients with chronic liver disease undergoing percutaneous liver biopsies and endoscopic retrograde cholangiopancreatography (ERCP). <i>Thromb Haemost</i> 2001;86(4):1125-1126.	Ineligible study design
Kotsi P, Gavalaki M, Anastasopoulou I, et al. The use of recombinant FVIIa (rFVIIa) in patients with uncontrollable surgical or post surgical bleeding. <i>Vox Sanguinis</i> 2006;91(Suppl 3):172.	No eligible outcomes
Kotze A. Recombinant activated factor VII in trauma: case report and review of published guidelines. <i>British Journal of Intensive Care</i> 2007;17(2):66-69.	Small sample size

Excluded article	Reason for exclusion
Kovesi T, Royston D. Pharmacological approaches to reducing allogeneic blood exposure. <i>Vox Sanguinis</i> 2003;84(1):2-10.	Ineligible study design
Kozek-Langenecker S. Management of massive operative blood loss. <i>Minerva Anestesiologica</i> 2007;73(7-8):401-415.	Ineligible study design
Krafft A, Asmis LM, Zimmermann R. Treatment of midgestational placental haemorrhage with recombinant factor VIIa. <i>Thrombosis and Haemostasis</i> . 2008;100(1):154-155.	Ineligible study design
Kretzschmar M, Zahm DM, Remmler K, et al. Pathophysiological and therapeutic aspects of amniotic fluid embolism (anaphylactoid syndrome of pregnancy): Case report with lethal outcome and overview. <i>Anaesthesist</i> 2003;52(5):419-426.	Ineligible study design
Kristeller JL. Recombinant factor VIIa attenuates bleeding due to enoxaparin. <i>Pharmacotherapy</i> 2003;23(10):1372.	Ineligible study design
Kristensen J, Alizadeh H, Shammas V, et al. Recombinant FVIIa effectively control bleedings when patients are properly selected. Retrospective analysis. <i>Haematologica-The Hematology Journal</i> 2008;93(Suppl 1):496	Small sample size
Kristensen J, Killander A, Hippe E, et al. Recombinant factor VIIa (rFVIIa) reduces the bleeding time in patients with thrombocytopenia. <i>Blood</i> 1993;82(10 Suppl 1).	Ineligible study design
Kristensen J, Killander A, Hippe E, et al. Clinical experience with recombinant factor VIIa in patients with thrombocytopenia. <i>Haemostasis</i> 1996;26 Suppl 1:159-164.	Ineligible study design
Ku G, Ting WC, Lim ST, et al. Life-threatening coagulopathy associated with use of Campath (alemtuzumab) in maintenance steroid-free renal transplant given before surgery. <i>Am J Transplant</i> 2008;8(4):884-886.	Ineligible study design
Kubisz P, Plamenova I, Chudej J, et al. Recombinant activated factor VIIa in patients at the high risk of bleeding. <i>Blood</i> 2003;102(11):103b.	Small sample size
Kubisz P, Stasko J. Recombinant activated factor VII in patients at high risk of bleeding. <i>Hematology</i> 2004;9(5-6):317-332.	Ineligible study design
Kulkarni R, Daneshmand A, Guertin S, et al. Successful use of activated recombinant factor VII in traumatic liver injuries in children. <i>Journal of Trauma-Injury Infection & Critical Care</i> 2004;56(6):1348-1352.	Small sample size
Kulkarni R, Daneshmand A, Guertin SR, et al. Successful use of recombinant factor VIIa (rFVIIa) in traumatic liver injuries in children. <i>Pediatric Research</i> 2002;51(4 Part 2):251A.	Small sample size
Kumar S, Badrinath HR. Early recombinant factor VIIa therapy in acute intracerebral hemorrhage: promising approach. <i>Neurol India</i> 2006;54(1):24-27.	Ineligible study design
Kumar S. Expansion of traumatic intracerebral hemorrhage: treatment implications with recombinant factor VIIa [comment]. <i>Neurology India</i> 2007;55(1):81.	Ineligible study design
Kurekci AE, Atay AA, Okutan V, et al. Recombinant activated factor VII for severe gastrointestinal bleeding after chemotherapy in an infant with acute megakaryoblastic leukemia. <i>Blood Coagulation & Fibrinolysis</i> 2005;16(2):145-147.	Ineligible study design
Labattaglia MP, Ihle B. Recombinant activated factor VII: current perspectives and Epworth experience. <i>Heart Lung Circ</i> 2007;16 Suppl 3:S96-S101.	Small sample size
Lacheva A, Georgiev S, Pilosoff V, et al. Administration of recombinant factor VIIa for the management of massive postoperative blood loss in children with congenital heart defects. <i>Anaesthesiology and Intensive Care</i> 2008;35(2):3-8.	Foreign language
Laffan M, O'Connell NM, Perry DJ, et al. Analysis and results of the recombinant factor VIIa extended-use registry. <i>Blood Coagulation & Fibrinolysis</i> 2003;14 Suppl 1:S35-S38.	Small sample size
Laffan MA, Cummins M. Recombinant factor VIIa for intractable surgical bleeding. <i>Blood</i> 2000;96(11 Part 2):85b.	Ineligible study design
Laffan MA, Tait RC, Blatny J, et al. Use of recombinant activated factor VII for bleeding in pancreatitis - A case series. <i>Pancreas</i> 2005;30(3):279-284.	Ineligible study design
Laffan MA, Tait RC, Blatny J, et al. Use of recombinant activated factor VII for bleeding in pancreatitis: a case series. <i>Pancreas</i> 2005;30(3):279-284.	Ineligible study design
Laird R, Carabine U. Recombinant factor VIIa for major obstetric haemorrhage in a Jehovah's Witness. <i>International Journal of Obstetric Anesthesia</i> 2008;17(2):193-194.	Ineligible study design
Lam MS, Sims-McCallum RP. Recombinant factor VIIa in the treatment of non-hemophiliac bleeding. <i>Ann Pharmacother</i> 2005;39(5):885-891.	Ineligible study design
Lam MSH, Sims-McCallum RP. Recombinant factor VIIa in the treatment of non-hemophiliac bleeding. <i>Annals of Pharmacotherapy</i> 2005;39(5):885-891.	Ineligible study design
Lamarche Y, Demers P, Poirier NC, et al. Safety and efficiency of recombinant activated factor VII in postcardiotomy massive hemorrhage. <i>Can J Cardiol</i> 2007;23(10):809-813.	Small sample size

Excluded article	Reason for exclusion
Langendonck L, Appel IM, van Kessel-Bakvis CL. Effective treatment with recombinant factor VIIa in a patient with storage pool deficiency. <i>Haemostasis</i> 2000;30(1-2):74.	Other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)
Lapchak PA, Araujo DM. Advances in hemorrhagic stroke therapy: conventional and novel approaches. <i>Expert Opinion on Emerging Drugs</i> 2007;12(3):389-406.	Ineligible study design
Laurian Y. Treatment of bleeding in patients with platelet disorders: Is there a place for recombinant factor VIIa? <i>Pathophysiology of Haemostasis and Thrombosis</i> 2002;32(Suppl 1):37-40.	Ineligible study design
Lawson JH, Murphy MP. Challenges for providing effective hemostasis in surgery and trauma. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):55-64.	Ineligible study design
Leblebisatan G, Sasmaz I, Antmen B, et al. Management of refractory hemorrhage in a kala-azar patient with thrombocytopenia and coagulopathy by using recombinant factor VIIa (rFVIIa). <i>Blood</i> 2005;106(11 Part 2):103B.	Ineligible study design
Leblebisatan G, Sasmaz I, Antmen B, et al. A successful use of recombinant factor VIIa in a patient with inhibitors, for bilateral cataract operation and circumcision. <i>Haemophilia</i> 2006;12(2):187-189.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Leblebisatan G, Sasmaz I, Mert K, et al. Management of refractory intracranial hemorrhage in a coagulopathic patient with liver disease by using recombinant factor VIIa (rFVIIa). <i>Blood</i> 2005;106(11 Part 2):102B-103B.	Small sample size
Lecumberri R, Panzio C, Paramo JA, et al. Acquired inhibitor of the intrinsic pathway in a non-haemophilic patient. Control of bleeding by recombinant factor VIIa. <i>Br J Haematol</i> 2002;119(1):284-285.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Lees K, Christensen MC, Raiko M, et al. Cost-effectiveness of recombinant activated factor VII in the treatment of acute intracerebral haemorrhage in the UK. <i>European Journal of Neurology</i> 2006;13(Suppl 2).	Ineligible study design
Leibovitch L, Kenet G, Mazor K, et al. Recombinant activated factor VII for life-threatening pulmonary hemorrhage after pediatric cardiac surgery. <i>Pediatric Critical Care Medicine</i> 2003;4(4):444-446.	Small sample size
Leung T, Han J, Hao Q, et al. The 9th International Symposium on Thrombolysis and Acute Stroke Therapy (TAST 2006), 2-3 December 2006 Hong Kong. <i>Int J Stroke</i> 2007;2(2):77-79.	Ineligible study design
Levi M, Bijsterveld NR, Keller TT. Recombinant factor VIIa as an antidote for anticoagulant treatment. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):65-69.	Ineligible study design
Levi M, Peters M, Buller HR. Efficacy and safety of recombinant factor VIIa for treatment of severe bleeding: a systematic review. <i>Critical Care Medicine</i> 2005;33(4):883-890.	Ineligible study design
Levi M, Vink R, de Jonge E. Prevention and treatment of bleeding by pro-hemostatic treatment strategies. <i>Wien Med Wochenschr</i> 2003;153(19-20):421-425.	Ineligible study design
Levi M. Efficacy and safety of prohemostatic agents. <i>Vox Sang</i> 2008;95(Suppl 1):35.	Ineligible study design
Levi M. Pathogenesis and treatment of DIC. <i>Thrombosis Research</i> 2005;115:54-55.	Not on rFVIIa
Levi M. Recombinant factor VIIa and trauma: treatment that does not leave you in the cold [comment]. <i>Journal of Thrombosis & Haemostasis</i> 2007;5(2):242-243.	Ineligible study design
Levi M. Recombinant factor VIIa: a general hemostatic agent? Not yet [comment]. <i>Journal of Thrombosis & Haemostasis</i> 2004;2(10):1695-1697.	Ineligible study design
Levi M. Use of recombinant factor VIIa in the perioperative period. <i>Hamostaseologie</i> 2009;29(1):68-70.	Ineligible study design
Levy JH, Fingerhut A, Brott T, et al. Recombinant factor VIIa in patients with coagulopathy secondary to anticoagulant therapy, cirrhosis, or severe traumatic injury: review of safety profile. <i>Transfusion</i> 2006;46(6):919-933.	Ineligible study design
Levy JH, Tamaka KA. Management of Surgical Hemostasis: Systemic Agents. <i>Vascular</i> 2008;16(Suppl 1):S14-S21.	Ineligible study design
Levy JH, Tanaka KA. Prohemostatic agents to prevent perioperative blood loss. <i>Semin Thromb Hemost</i> 2008;34(5):439-444.	Ineligible study design
Levy JH, Tanaka KA. The anticoagulated patient: Strategies for effective blood loss management. <i>Surgery (St Louis)</i> 2007;142(4 Suppl S):S71-S77.	Ineligible study design
Levy JH. Hemostatic agents. <i>Transfusion (Malden)</i> 2004;44(12 Suppl S):58S-62S.	Ineligible study design

Excluded article	Reason for exclusion
Levy JH. Massive transfusion coagulopathy. <i>Seminars in Hematology</i> 2006;43(1 Suppl 1):S59-S63.	Ineligible study design
Levy JH. Novel concepts in treatment and prevention of bleeding. <i>Anesthesia & Analgesia</i> 2005(Suppl. S):43-47.	Ineligible study design
Levy JH. Overview of clinical efficacy and safety of pharmacologic strategies for blood conservation. <i>American Journal of Health-System Pharmacy</i> 2005;62(18 Suppl 4):S15-S19.	Ineligible study design
Levy JH. Pharmacologic methods to reduce perioperative bleeding. <i>Transfusion</i> 2008;48(1 Suppl):31S-38S.	Ineligible study design
Levy JH. Pharmacologic preservation of the hemostatic system during cardiac surgery. <i>Annals of Thoracic Surgery</i> 2001;72(5):S1814-S1820.	Ineligible study design
li c-c, wang j-h, huang y-t, et al. Clinical experiences with recombinant activated factor VII for managing uncontrolled hemorrhage in non-hemophilic patients. <i>Tzu Chi Med J</i> 2007;19(4):220-225.	Ineligible study design
Libman RB, Lungu C, Kwiatkowski T. Multiple ischemic strokes associated with use of recombinant activated factor VII. <i>Archives of Neurology</i> 2007;64(6):879-881.	Small sample size
Lichtman AD, Carullo V, Minhaj M, et al. Case 6--2007: massive intraoperative thrombosis and death after recombinant activated factor VII administration. <i>Journal of Cardiothoracic & Vascular Anesthesia</i> 2007;21(6):897-902.	Small sample size
Liebekind DS. American Stroke Association--28th International Conference. 13-15 February 2003, Phoenix, AZ, USA. <i>IDrugs</i> . 2003;6(4):288-289.	Ineligible study design
Liem AK, Biesma DH, Ernst SM, et al. Recombinant activated factor VII for false aneurysms in patients with normal haemostatic mechanisms. <i>Thromb Haemost</i> 1999;82(1):150-151.	Small sample size
Lin J, Hanigan WC, Tarantino M, et al. The use of recombinant activated factor VII to reverse warfarin-induced anticoagulation in patients with hemorrhages in the central nervous system: preliminary findings. <i>Journal of Neurosurgery</i> 2003;98(4):737-740.	Small sample size
Lisman T, Leebeek FW, Meijer K, et al. Recombinant factor VIIA improves clot formation but not TAFI-mediated downregulation of fibrinolysis in patients with cirrhosis and during liver transplantation. <i>Hepatology</i> 2001;34(4 Pt 2):191A.	Duplicate
Liu-DeRyke X, Rhoney D. Hemostatic therapy for the treatment of intracranial hemorrhage. <i>Pharmacotherapy</i> 2008;28(4):485-495.	Ineligible study design
Lloyd JV, Joist JH. Recombinant factor VIIa: a universal hemostatic agent? <i>Curr Hematol Rep</i> 2002;1(1):19-26.	Ineligible study design
Lodge JPA, Jonas S, Jones RM, et al. Efficacy and safety of recombinant factor VIIa (rFVIIa) on transfusion reduction in orthotopic liver transplantation (OLT) - a randomised, double-blind, placebo-controlled trial. <i>Transplantation</i> 2004;78(2).	Duplicate
Lodge JPA. Hemostasis in liver resection surgery. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):70-75.	Ineligible study design
Lodge P, Jonas S, Jaeck D, et al. Recombinant factor VIIa (NOVOSEVEN) in partial hepatectomy: a randomized, placebo-controlled, double-blind clinical trial [abstract]. <i>Hepatology</i> 2002;36(4 Pt 2).	Duplicate
Loertzer H, Soukup J, Fornara P. Rapid reversal of coagulopathy in patients on platelet aggregation inhibitors immediately prior to renal transplantation with recombinant factor VIIa? <i>Transpl Int</i> 2006;19(6):519-520.	Ineligible study design
Loertzer H, Soukup J, Fornara P. Recombinant factor VIIa reduces bleeding risk in patients on platelet aggregation inhibitors immediately prior to renal transplantation--a retrospective analysis. <i>Urol Int</i> 2007;78(2):135-139.	Ineligible study design
Loudon B, Smith MP. Recombinant factor VIIa as an adjunctive therapy for patients requiring large volume transfusion: a pharmacoeconomic evaluation. <i>Internal Medicine Journal</i> 2005;35(8):463-467.	Ineligible study design
Loudon B, Smith MP. Recombinant factor VIIa as an adjunctive therapy for patients requiring large volume transfusion: a pharmacoeconomic evaluation. <i>Internal Medicine Journal</i> 35(8):463-467.	Ineligible study design
Louie R, Thomas B, Irwin R, et al. rFVIIa and obstructive hydronephrosis. <i>Pediatric Blood & Cancer</i> 2008;50(2):431.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)

Excluded article	Reason for exclusion
Louie R, Thomas B, Irwin R. rFVIIa and obstructive hydronephrosis. <i>Pediatr Blood Cancer</i> 2008;50(2):431.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Lowe R. Trial of haemophilia treatment for intracerebral haemorrhage [erratum appears in <i>Lancet Neurol</i> 2004 Nov 4;3(11):644 Note: dosage error in text]. <i>Lancet Neurology</i> 2004;3(8):448.	Ineligible study design
Lucey MA, Myburgh JA. Recombinant activated factor VII for exsanguinating haemorrhage post bilateral lung transplantation for extra-corporeal lung support-dependent respiratory failure. <i>Anaesth Intensive Care</i> 2003;31(4):465-469.	Ineligible study design
Lucia JF, Orna E, Allepuz C, et al. Successful outcome of a cirrhotic patient with postoperative hematuria treated with a high single dose of recombinant activated factor VII (rFVIIa). <i>Blood</i> 2001;98(11 Part 2):82b.	Ineligible study design
Ludlam CA. The evidence behind inhibitor treatment with recombinant factor VIIa. <i>Pathophysiology of Haemostasis & Thrombosis</i> 2002;32 Suppl 1:13-18.	Ineligible study design
Lund-Hansen T. NovoSeven--virus safety. <i>Haemostasis</i> 1996;26 Suppl 1:96-97.	Animal or in-vitro study
Lusher JM. Recombinant activated factor VII for treatment of intramuscular haemorrhages: a comparison of early versus late treatment. <i>Blood Coagul Fibrinolysis</i> 1998;9 Suppl 1:S111-S114.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Lusher JM. Recombinant clotting factors: a review of current clinical status. <i>Biodrugs</i> 2000;13(4):289-298.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Lusher JM. rFVIIa: Results of a double-blind dose-finding study. <i>Transfusion</i> 1994;34(8).	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Lynn M, Jeroukhimov I, Klein Y, et al. Updates in the management of severe coagulopathy in trauma patients. <i>Intensive Care Medicine</i> 2002;28 Suppl 2:S241-S247.	Ineligible study design
Ma B, Wang ZN, Zhang BR. Effect of recombinant activated factor VII a on early recovery of patients undergoing cardiac valve replacement under cardiopulmonary bypass: a randomized double-blind placebo-controlled trial. <i>Dier Junyi Daxue Xuebao</i> 2006;27(10):1110-1113.	Foreign language
Macdonald JA, Fraser JF, Foot CL, et al. Successful use of recombinant factor VII in massive hemoptysis due to community-acquired pneumonia. <i>Chest</i> 2006;130(2):577-579.	Ineligible study design
Maciej K, Ina BK, Slawomir Z, Lukasz K. Use of small doses of recombinant factor VIIa during scoliosis surgery. <i>The Journal of Bone and Joint Surgery</i> 2004;86-B(Suppl 1):94-99a.	Duplicate
Mackonochie M, Chan D. Oral and poster presentations. 13-17 March 2005, San Diego, CA, USA. <i>IDrugs</i> . 2005;8(4):285-287.	Not on rFVIIa
MacLaren R, Weber LA, Brake H, et al. A multicenter assessment of recombinant factor VIIa off-label usage: clinical experiences and associated outcomes. <i>Transfusion</i> 2005;45(9):1434-1442.	Data combined for multiple conditions
MacLaren R. Key concepts in the management of difficult hemorrhagic cases. <i>Pharmacotherapy</i> 2007;27(9 Pt 2):93S-102S.	Ineligible study design
Madjdinasab NN, Sharafaddinzadeh N, Mohamadianejad E, et al. Effect of Novoseven on hospitalization duration of Iranian ICH patients. <i>Cerebrovascular Diseases</i> 2008;25(Suppl 2):158.	No usable data
Magnetti S, Oinonen M, Matuszewski KA. An evaluation of off-label use of recombinant activated human factor VII (NovoSeven): patient characteristics, utilization trends, and outcomes from an electronic database of U S academic health centers. <i>P & T</i> 32(4):218-220.	Ineligible study design
Magnetti S, Oinonen M, Matuszewski KA. An evaluation of off-label use of recombinant activated human factor VII (NovoSeven): Patient characteristics, utilization trends, and outcomes from an electronic database of U.S. academic health centers. <i>P&T</i> 2007;32(4):218-230.	Data combined for multiple conditions
Mahdy AM, Webster NR. Perioperative systemic haemostatic agents. <i>British Journal of Anaesthesia</i> 2004;93(6):842-858.	Ineligible study design

Excluded article	Reason for exclusion
Mahmoud A, Al-Ruzzeh S, McKeague H, et al. Systemic venous thrombosis after recombinant factor VIIa in the control of bleeding after cardiac surgery. <i>Tex Heart Inst J</i> 2007;34(4):485-488.	Small sample size
Makris M, Kitchen S, Russell F, et al. Clinical use of activated recombinant factor VII concentrate rFVIIa and its in-vivo monitoring. <i>British Journal of Haematology</i> 1990;76(Suppl 1):9.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Makris M, Van Veen JJ. Comparative thrombotic event incidence after infusion of recombinant factor VIIa versus factor VIII inhibitor bypass activity--a rebuttal. <i>J Thromb Haemost</i> 2005;3(4):818-819; author reply 819.	Ineligible study design
Malato A, Lo Monte AI, Anastasio R, et al. Successful treatment of gastrointestinal bleeding with recombinant factor VIIa after kidney transplantation in patients with pancytopenia. <i>Transplant Proc</i> 2006;38(4):1031-1033.	Ineligible study design
Malherbe S, Tsui BCH, Stobart K, et al. Argatroban as anticoagulant in cardiopulmonary bypass in an infant and attempted reversal with recombinant activated factor VII [see comment]. <i>Anesthesiology</i> 2004;100(2):443-445.	Small sample size
Mallarkey G, Brighton T, Thomson A, et al. An evaluation of eptacog alfa in nonhaemophiliac conditions. <i>Drugs</i> 2008;68(12):1665-1689.	Ineligible study design
Mandell BF. Messing with mother nature [comment]. <i>Cleveland Clinic Journal of Medicine</i> 2005;72(4):265.	Ineligible study design
Manning BJ, Hynes N, Courtney DF, et al. Recombinant factor VIIa in the treatment of intractable bleeding in vascular surgery. <i>European Journal of Vascular & Endovascular Surgery</i> 2005;30(5):525-527.	Ineligible study design
Mannucci PM, Levi M. Prevention and treatment of major blood loss. <i>N Engl J Med</i> 2007;356(22):2301-2311.	Ineligible study design
Mannucci PM. Intracerebral haemorrhage and recombinant factor VIIa: not so good news! <i>Internal & Emergency Medicine</i> 2007;2(3):235-236.	Ineligible study design
Marietta M, Facchini L, Girardis M, et al. More on: Platelet count and the use of recombinant factor VIIa for the treatment of bleeding complications after hematopoietic stem cell transplantation [comment]. <i>Journal of Thrombosis & Haemostasis</i> 2006;4(1):288.	Ineligible study design
Marietta M, Facchini L, Pedrazzi P, et al. Pathophysiology of bleeding in surgery. <i>Transplantation Proceedings</i> 2006;38(3):812-814.	Ineligible study design
Marietta M, Pedrazzi P, Girardis M, et al. Intracerebral haemorrhage: an often neglected medical emergency. <i>Internal & Emergency Medicine</i> 2007;2(1):38-45.	Ineligible study design
Markiewicz M, Kalicinski P, Kaminski A, et al. Acute coagulopathy after reperfusion of the liver graft in children correction with recombinant activated factor VII. <i>Transplant Proc</i> 2003;35(6):2318-2319.	Small sample size
Marson F, Farnia A, Callegher L, et al. Use of recombinant activated factor VII (rFVIIa-NovoSeven) in the treatment of uncontrolled postsurgical hemorrhage in a patient with deep venous thrombosis and caval filter. A case report. <i>Minerva Anestesiol</i> 2006;72(7-8):675-682.	Ineligible study design
Marti-Carvajal A, Salanti G, Marti-Carvajal P. Human recombinant activated factor VII for upper gastrointestinal bleeding in patients with liver diseases [Systematic Review]. <i>Cochrane Database of Systematic Reviews</i> 2008(2).	Ineligible study design
Marti-Carvajal AJ, Salanti G, Marti-Carvajal PI. Human recombinant activated factor VII for upper gastrointestinal bleeding in patients with liver diseases. <i>Cochrane Database Syst Rev</i> 2007(1):CD004887.	Ineligible study design
Martinez J, Cid AR, de la Rubia J, et al. Treatment of intra-abdominal bleeding with recombinant activated factor VII in a patient with disseminated intravascular coagulation secondary to septic shock. <i>Blood Coagulation & Fibrinolysis</i> 2005;16(4):297-299.	Ineligible study design
Martinowitz U, Kenet G, Lubetski A, et al. Possible role of recombinant activated factor VII (rFVIIa) in the control of hemorrhage associated with massive trauma. <i>Canadian Journal of Anaesthesia</i> 2002;49(10):S15-S20.	Duplicate
Martinowitz U, Kenet G, Luboshitz J, et al. Recombinant FVIIa (rFVIIa) for salvage of surgical patients suffering uncontrolled bleeding. <i>Blood</i> 1999;94(10 Suppl 1 Part 1):461a.	Small sample size
Martinowitz U, Kenet G, Segal E, et al. Recombinant activated factor VII for adjunctive hemorrhage control in trauma. <i>Journal of Trauma-Injury Infection & Critical Care</i> 2001;51(3):431-438; discussion 438-439.	Small sample size

Excluded article	Reason for exclusion
Martinowitz U, Luboshitz J, Lubetsky A, et al. New approach for the management of catastrophic bleeds in trauma and surgery: Enhancement of coagulation at the site of injury by recombinant activated factor VII (rFVIIa). <i>Blood</i> 2001;98(11 Part 1):827a-828a.	Small sample size
Martinowitz U, Schulman S. Coagulation factor concentrates by continuous infusion. <i>Transfusion Medicine Reviews</i> 1997;11(1):56-63.	Animal or in-vitro study
Martinowitz U, Zaarur M, Yaron BL, et al. Treating traumatic bleeding in a combat setting: possible role of recombinant activated factor VII. <i>Mil Med</i> 2004;169(12 Suppl):16-18, 4.	Ineligible study design
Matevosyan K, Madden C, Aung FM, et al. Management of Warfarin Associated Intracranial Hemorrhage with a 3-Factor Prothrombin Complex Concentrate and Low Dose Recombinant Factor VIIa. <i>Blood</i> 2008;112(11):1165-1166	No usable data
Matherne D, Begtrup K, Grotta J. Validation of the ICH score in the recombinant factor VIIa ICH trial. <i>Neurology</i> 2007;68(12 Suppl 1):A220-A221.	Duplicate
Mathew P, Simon TL, Hunt KE, et al. How we manage requests for recombinant factor VIIa (NovoSeven). <i>Transfusion</i> 2007;47(1):8-14.	Ineligible study design
Mathew P, Winter SS, Frost JD, et al. Novel applications of recombinant factor VIIa for the management of pediatric coagulopathic diseases. <i>Journal of Pediatric Hematology/Oncology</i> 2003;25(6):499-502.	Small sample size
Mathew P, Winter SS, Frost JD, et al. Successful control of pediatric coagulopathic diseases using recombinant factor VIIa (rFVIIa). <i>Blood</i> 2001;98(11 Part 2):82b-83b.	Small sample size
Mathew P, Young G. Recombinant factor VIIa in paediatric bleeding disorders--a 2006 review. <i>Haemophilia</i> 2006;12(5):457-472.	Ineligible study design
Mathew P. The use of rFVIIa in non-haemophilia bleeding conditions in paediatrics. A systematic review. <i>Thrombosis & Haemostasis</i> 2004;92(4):738-746.	Ineligible study design
Matic I, Titlic M, Lucic I, et al. Recombinant activated factor VII in refractory gastrointestinal haemorrhage of unknown aetiology. <i>Bratislavske Lekarske Listy</i> 2008;109(10):438-440.	Ineligible study design
Matijevic V, Supe S, Poljakovic Z, et al. Treatment with rFVIIa (NovoSeven) in acute intracerebral hemorrhage. <i>Neurologia Croatica</i> 2007;56(3/4):59-68.	Small sample size
Mausser-Bunschoten EP, de Goede-Bolder A, Koopman MMW, et al. Different efficacy of continuous infusion of recombinant factor VIIa in dental surgery compared to other bleeds and surgical interventions. <i>Blood</i> 1999;94(10 Suppl 1 Part 2):120b.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Mayer S, Brun N, Skolnick B. Randomized, double-blind, placebo-controlled, multi-center, parallel groups study to evaluate the efficacy and safety of activated recombinant factor VII in acute intracerebral hemorrhage. 28th International Stroke Conference. 2003.	Duplicate
Mayer S, Brun N. Safety and preliminary efficacy of activated recombinant factor VII in acute intracerebral hemorrhage. <i>Stroke</i> 2003;34(1).	Duplicate
Mayer SA, Broderick J, Davis S, et al. The FAST trial: randomised, placebo-controlled, double-blind, multicenter, phase III study to assess recombinant activated factor VII efficacy in acute intracerebral haemorrhage. International Stroke Conference 2006.	Duplicate
Mayer SA, Brun N, Broderick J, et al. Safety and preliminary efficacy of recombinant coagulation factor VIIa in acute intracerebral hemorrhage: US Phase 2A Study. <i>Stroke</i> 2004;35(1).	Duplicate
Mayer SA, Brun N, Broderick J, et al. Predictors and clinical impact of hematoma growth in the NovoSeven ICH Trial. <i>European Journal of Neurology</i> 2004;11(Suppl 2).	Duplicate
Mayer SA, Brun N, Broderick J, et al. Recombinant factor VIIa for acute intracerebral hemorrhage. <i>Stroke</i> 2004;35(6).	Duplicate
Mayer SA, Brun NC, Begtrup K, et al. Randomized, placebo-controlled, double-blind phase III study to assess rFVIIa efficacy in acute intracerebral hemorrhage: the FAST trial. <i>Cerebrovascular Diseases</i> 2007;23(Suppl 2).	Duplicate
Mayer SA, Brun NC, Broderick JP, et al. Recombinant factor VIIa for acute intracerebral haemorrhage: impact of timing of treatment. <i>International Journal of Stroke</i> 2006;1(Suppl 1).	Ineligible study design
Mayer SA, Brun NC. Safety and feasibility of ultra-early hemostatic therapy for intracerebral hemorrhage: The NovoSeven ICH Trial. 27th International Stroke Conference 2002.	Duplicate
Mayer SA, Committee FTS. Complications in patients with intracerebral hemorrhage treated with recombinant factor VIIa [comment]. <i>Neurology</i> 2007;69(3):319-320.	Ineligible study design

Excluded article	Reason for exclusion
Mayer SA, Davis SM, Begtrup K, et al. Subgroup analysis in the Fast trial: a subset of intracerebral hemorrhage patients that benefit from recombinant activated factor VII? <i>Stroke</i> 2008;39(2):528.	Duplicate
Mayer SA, Davis SM, Skolnick BE, et al. Can a subset of intracerebral hemorrhage patients benefit from hemostatic therapy with recombinant activated factor VII? <i>Stroke</i> 2009;40(3):833-840.	Duplicate
Mayer SA, Rincon F. Treatment of intracerebral haemorrhage. <i>Lancet Neurol</i> 2005;4(10):662-672.	Ineligible study design
Mayer SA, Rincon F. Ultra-early hemostatic therapy for acute intracerebral hemorrhage. <i>Seminars in Hematology</i> 2006;43(1 Suppl 1):S70-S76.	Duplicate
Mayer SA. Intracerebral hemorrhage: natural history and rationale of ultra-early hemostatic therapy. <i>Intensive Care Medicine</i> 2002;28 Suppl 2:S235-S240.	Ineligible study design
Mayer SA. NovoSeven intracerebral hemorrhage trial. <i>Stroke</i> 2002;33(10).	Duplicate
Mayer SA. Recombinant activated factor VII for acute intracerebral hemorrhage. <i>Stroke</i> 2007;38(2 Suppl):763-767.	Duplicate
Mayer SA. Ultra-early hemostatic therapy for intracerebral hemorrhage. <i>Stroke</i> 2003;34(1):224-229.	Ineligible study design
Mayer SA. Ultra-early hemostatic therapy for primary intracerebral hemorrhage: a review. <i>Canadian Journal of Neurological Sciences</i> 2005;32 Suppl 2:S31-S37.	Ineligible study design
Mayo A, Misgav M, Kluger Y, et al. Recombinant activated factor VII (NovoSeven): addition to replacement therapy in acute, uncontrolled and life-threatening bleeding. <i>Vox Sanguinis</i> 2004;87(1):34-40.	Small sample size
Mazer CD, Leong-Poi H, Mahoney J, et al. Vascular injury and thrombotic potential: a note of caution about recombinant factor VIIa. <i>Seminars in Cardiothoracic & Vascular Anesthesia</i> 2007;11(4):261-264.	Ineligible study design
Mazzara R, Escolar G, Castillo R, Ordinas A. Alternatives to platelet transfusions. <i>Sangre (Saragossa)</i> 1998;43(4):331-338.	Ineligible study design
McCabe CJ, Warren RL. Trauma: an annotated bibliography of the recent literature--2005. <i>American Journal of Emergency Medicine</i> 2006;24(5):517-539.	Ineligible study design
McClelland 3 rd S, Won EK, Lam CH. Utilization of recombinant activated factor VII for intracranial hematoma evacuation in coagulopathic nonhemophilic neurosurgical patients with normal international normalized ratios. <i>Neurocrit Care</i> 2007;7(2):136-139.	Small sample size
McCloy M, Iverson A, Crawley C, Laffan M. Recombinant activated factor VIIa for intractable haematuria in sickle cell disease. <i>CME Bulletin Haematology</i> 2000;3(2):42-44.	Ineligible study design
McCormick PA, Murphy KM. Splenomegaly, hypersplenism and coagulation abnormalities in liver disease. <i>Best Practice & Research in Clinical Gastroenterology</i> 2000;14(6):1009-1031.	Ineligible study design
McDonald V, Ryland K. Coagulopathy in trauma: optimising haematological status. <i>Trauma</i> 2008;10:109-123.	Ineligible study design
McEwan A. Aspects of bleeding after cardiac surgery in children. <i>Paediatr Anaesth</i> 2007;17(12):1126-1133.	Ineligible study design
McIlroy DR, Silvers AJ. Recombinant factor VIIa for life-threatening bleeding in high-risk cardiac surgery despite full-dose aprotinin. <i>Anesth Analg</i> 2004;99(1):27-30.	Small sample size
McLeod A, Karkouti K, Yeo E, et al. Recombinant factor VIIa (rF-VIIa) for intractable blood loss after cardiac surgery: A single-arm pilot trial in twenty patients. <i>Blood</i> 2003;102(11):308a.	No eligible outcomes
McLintock C. Postpartum haemorrhage. <i>Thrombosis Research</i> 2005;115 Suppl 1:65-68.	Ineligible study design
McMorrow RC, Ryan SM, Blunnie WP, et al. Use of recombinant factor VIIa in massive post-partum haemorrhage. <i>European Journal of Anaesthesiology</i> 2008;25(4):293-298.	Duplicate
McMullin NR, Kauvar DS, Currier HM, et al. The clinical and laboratory response to recombinant factor VIIa in trauma and surgical patients with acquired coagulopathy. <i>Current Surgery</i> 2006;63(4):246-251.	Data combined for multiple conditions
McPherson J, Sutcharitchan P, Lloyd J, et al. Experience with continuous infusion of recombinant activated factor VII in the Asia-Pacific region. <i>Blood Coagul Fibrinolysis</i> 2000;11 Suppl 1:S31-S34.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
McRoberts RJ, Beard D, Walsh TS. A study of blood product use in patients with major trauma in Scotland: analysis of a major trauma database. <i>Emergency Medicine Journal</i> 2007;24(5):325-329.	No usable data

Excluded article	Reason for exclusion
Mealy NE, Bayes M. Eptacog alfa (activated). <i>Drugs of the Future</i> . 2005;30(5):528-530.	Ineligible study design
Meijer K, Hendriks HGD, De Wolf JTM, et al. Recombinant factor VIIa in orthotopic liver transplantation: influence on parameters of coagulation and fibrinolysis. <i>Blood Coagulation & Fibrinolysis</i> 2003;14(2):169-174.	Duplicate
Mendez P, Acebo W, Jeffers L, et al. Incidence of subcapsular and intrahepatic hematoma following laparoscopic liver biopsy after intravenous factor VIIa administration in cirrhotic patients with coagulopathy [abstract]. <i>Hepatology</i> 1998;28(Suppl 4).	Other: unpublished data
Mercer KW, Gail Macik B, Williams ME. Hematologic disorders in critically ill patients. <i>Seminars in Respiratory & Critical Care Medicine</i> . 2006;27(3):286-296.	Ineligible study design
Mercier FJ, Van de Velde M. Major obstetric hemorrhage. <i>Anesthesiology Clinics</i> 26(1):53-66.	Ineligible study design
Miall FM, Barton LM, Ayyash R, et al. Recombinant activated factor VII (rVIIa): Predicting response in intractable bleeding. <i>British Journal of Haematology</i> 2005;129(Suppl 1):20.	No eligible outcomes
Michalska-Krzanowska G, Czuprynska M. Recombinant factor VII (activated) for haemorrhagic complications of severe sepsis treated with recombinant protein C (activated). <i>Acta Haematol</i> 2006;116(2):126-130.	Ineligible study design
Michalska-Krzanowska G, Sajdak R, Stasiak-Pikula E. Effects of recombinant factor VIIa in haemorrhagic complications of urological operations. <i>Acta Haematol</i> 2003;109(3):158-160.	Small sample size
Mieli G, Tosi P, Marcheselli S, et al. Early haemostatic therapy for spontaneous intracranial haemorrhage. <i>Neurological Sciences</i> 2005;26 Suppl 1:S34-S36.	Ineligible study design
Midathada MV, Mehta P, Waner M, et al. Recombinant factor VIIa in the treatment of bleeding. <i>Am J Clin Pathol</i> 2004;121(1):124-137.	Ineligible study design
Millar CG, Stringer MD, Sugarman I, et al. The use of recombinant factor VIIa for bleeding in paediatric practice. <i>Haemophilia</i> 2005;11(2):171-174.	Ineligible study design
Mindikoglu AL, Anantharaju A, George M, et al. Splenic embolization in a Jehovah's Witness: role of recombinant human factor VIIa. <i>Hepatogastroenterology</i> 2003;50(53):1697-1699.	Ineligible study design
Mindikoglu AL, Anantharaju A, George M, et al. Acute intracranial hemorrhage in a cirrhotic controlled with recombinant factor VIIa. <i>Dig Dis Sci</i> 2003;48(6):1130-1135.	Small sample size
Mindikoglu AL, Anantharaju A, Villanueva J, et al. Pericardiocentesis and pancreatic aspiration needle biopsy in coagulopathic and thrombocytopenic cirrhotic patient. <i>Chest</i> 2003;123(3):956-958.	Ineligible study design
Minniti C, Weinthal J. Use of recombinant activated factor VII (rFVIIa) in two children with idiopathic thrombocytopenic purpura (ITP). <i>Blood</i> 2001;98(11 Part 2):62b.	Ineligible study design
Mitchell JG, Speake WJ, Russell NK, et al. Recombinant factor VIIa: a useful tool for life-threatening colonic bleeding. Report of a case. <i>Dis Colon Rectum</i> 2007;50(12):2238-2240.	Ineligible study design
Mittal S, Watson HG. A critical appraisal of the use of recombinant factor VIIa in acquired bleeding conditions. <i>Br J Haematol</i> 2006;133(4):355-363.	Ineligible study design
Moeller MS. Indications for use of recombinant factor VIIa: a case study with implications for research. <i>Journal of Trauma Nursing</i> 2006;13(4):190-192.	Small sample size
Mohr AM, Holcomb JB, Dutton RP, et al. Recombinant activated factor VIIa and hemostasis in critical care: a focus on trauma. <i>Critical Care (London, England)</i> 2005;9 Suppl 5:S37-S42.	Ineligible study design
Mohr JP. Report of the 16th European Stroke Conference, Glasgow, May 29 to June 1, 2007. <i>Cerebrovasc Dis</i> 2007;24(4):385-386.	Ineligible study design
Moisescu E, Ardelean L, Simion I, et al. Recombinant factor VIIa treatment of bleeding associated with acute renal failure. <i>Blood Coagul Fibrinolysis</i> 2000;11(6):575-577.	Ineligible study design
Molskov Bech RB, Nielsen L, Falch JF, et al. Evaluation of efficacy of recombinant factor VIIa in 149 patients treated for critical bleeds. <i>Blood</i> 1994;84(10 Suppl 1):68A.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Moltzan CJ, Anderson DA, Callum J, et al. The evidence for the use of recombinant factor VIIa in massive bleeding: development of a transfusion policy framework. <i>Transfusion Medicine</i> 2008;18(2):112-120.	Duplicate
Monroe DM, Hoffman M, Allen GA, et al. The factor VII-platelet interplay: Effectiveness of recombinant factor VIIa in the treatment of bleeding in severe thrombocytopathia. <i>Seminars in Thrombosis and Hemostasis</i> 2000;26(4):373-377.	Ineligible study design

Excluded article	Reason for exclusion
Monroe DM, Roberts HR. Mechanism of action of high-dose factor VIIa: points of agreement and disagreement. <i>Arterioscler Thromb Vasc Biol</i> 2003;23(1):8-9; discussion 10.	In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
Monroe DM. Modeling the action of factor VIIa in dilutional coagulopathy. <i>Thrombosis Research</i> 2008;122(Suppl 1):S7-S10.	Animal or in-vitro study
Moondi P, Cordingley J, Pepper J. Successful use of recombinant factor VIIa for the management of severe haemorrhage after cardiac surgery. <i>British Journal of Intensive Care</i> 2004;14(4):136-138.	Ineligible study design
Morante L, Guasch EV, Palacio F, et al. Activated recombinant factor VII to reverse oral anticoagulants for emergent cesarean delivery. <i>Anesth Analg</i> 2006;102(6):1902-1903.	Ineligible study design
Morenski JD, Tobias JD, Jimenez DF. Recombinant activated factor VII for cerebral injury-induced coagulopathy in pediatric patients. Report of three cases and review of the literature. <i>Journal of Neurosurgery</i> 2003;98(3):611-616.	Small sample size
Morey AF. Factor VIIa for correction of traumatic coagulopathy. <i>J Urol</i> 2005;174(3):968.	Ineligible study design
Morris S, Ridley S, Munro V, et al. Cost effectiveness of recombinant activated factor VII for the control of bleeding in patients with severe blunt trauma injuries in the United Kingdom. <i>Anaesthesia</i> 2007;62(1):43-52.	Ineligible study design
Morris S, Ridley S, Munro V, et al. Cost effectiveness of recombinant activated factor VII for the control of bleeding in patients with severe blunt trauma injuries in the United Kingdom. <i>Anaesthesia</i> 62(1):43-52.	Ineligible study design
Moscardo F, Perez F, de la Rubia J, et al. Successful treatment of severe intra-abdominal bleeding associated with disseminated intravascular coagulation using recombinant activated factor VII. <i>Br J Haematol</i> 2001;114(1):174-176.	Ineligible study design
Mossad EB, Machado S, Apostolakis J. Bleeding following deep hypothermia and circulatory arrest in children. <i>Semin Cardiothorac Vasc Anesth</i> 2007;11(1):34-46.	Ineligible study design
Mousa SA. Tissue factor/VIIa in thrombosis and cancer. <i>Methods Mol Med</i> 2004;93:119-132.	Not on rFVIIa
Muirhead B, Dickson T, Freedman J, et al. 473649-recombinant factor v11a use in Canada. <i>Canadian Journal of Anaesthesia</i> 2008;55 Suppl 1:473649.	No usable data
Muleo G, Santoro R, Iannaccaro PG, et al. Small doses of recombinant factor VIIa in acquired deficiencies of vitamin K dependent factors. <i>Blood Coagul Fibrinolysis</i> 1999;10(8):521-522.	Small sample size
Murkin JM. A novel hemostatic agent: the potential role of recombinant activated factor VII (rFVIIa) in anesthetic practice. <i>Canadian Journal of Anaesthesia</i> 2002;49(10):S21-S26.	Ineligible study design
Muslimani A, Daw H. Using recombinant activated factor VII (rFVIIa) in refractory bleeding: A community hospital experience. <i>Blood</i> 2006;108(11 Part 2):90B-91B.	Ineligible study design
Muslimani AA, Walia HK, Ahluwalia MS, Daneschvar HL, Daw HA. Successful use of recombinant factor VIIa in reversal of life threatening bleeding caused by coagulopathy. <i>Blood</i> 2005;106(11 Part 2):100B.	Ineligible study design
Nadir Y, Brenner B. Hemorrhagic and thrombotic complications in bone marrow transplant recipients. <i>Thrombosis Research</i> 2007;120(Suppl 2):S92-S98.	Ineligible study design
Nagarsheth NP, Shander A, Malovany R, et al. Bloodless surgery in a Jehovah's Witness patient with a 12.7-kg uterine leiomyosarcoma. <i>J Surg Educ</i> 2007;64(4):212-219.	Ineligible study design
Naik VN, Mazer CD, Latter DA, et al. Successful treatment using recombinant factor VIIa for severe bleeding post cardiopulmonary bypass. <i>Can J Anaesth</i> 2003;50(6):599-602.	Small sample size
Narayan RK, Maas AIR, Marshall LF, et al. Recombinant factor VIIa in traumatic intracerebral hemorrhage: results of a dose-escalation clinical trial. <i>Neurosurgery</i> 2008;62(4):776-786; discussion 786-788.	Duplicate
National Horizon Scanning Centre. Recombinant factor VIIa in haemostasis - horizon scanning review (Brief record). <i>Health Technology Assessment Database</i> 2009; Issue 3	Duplicate
Negrier C, Dargaud Y, Bordet JC. Basic aspects of bypassing agents. <i>Haemophilia</i> 2006;12 Suppl 6:48-52; discussion 52-53.	In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
Negrier C, Lienhart A. Overall experience with NovoSeven. <i>Blood Coagul Fibrinolysis</i> 2000;11 Suppl 1:S19-S24.	Ineligible study design

Excluded article	Reason for exclusion
Nelson SC, Heisel MA, Christie B, et al. Use of recombinant factor VIIA in children undergoing radioactive synovectomy. <i>Blood</i> 1995;86(10 Suppl 1):882A.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Neubauer P, Mursula A. <i>Biotechnology - 12th European Congress. Idrugs.</i> 2005;8(10):809-812.	Ineligible study design
Ng HJ, Koh LP, Lee LH. Successful control of postsurgical bleeding by recombinant factor VIIa in a renal failure patient given low molecular weight heparin and aspirin. <i>Ann Hematol</i> 2003;82(4):257-258.	Ineligible study design
Ng HJ, Loh SM, Tan DC, et al. Thrombosis associated with the use of recombinant activated factor VII: profiling two events. <i>Thromb Haemost</i> 2004;92(6):1448-1449.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Ng SS, Yiu RY, Lee JF, et al. Portal venous gas and thrombosis in a Chinese patient with fulminant Crohn's colitis: a case report with literature review. <i>World J Gastroenterol</i> 2006;12(34):5582-5586.	Ineligible study design
Nga HJ, Crowther MA. New anti-thrombotic agents: Emphasis on hemorrhagic complications and their management. <i>Seminars in Hematology</i> 2006;43(1 Suppl 1):S77-S83.	Ineligible study design
Nicklin J, Perrin L, Crandon A, et al. Re: Guidelines for the use of recombinant activated factor VII in massive obstetric haemorrhage. <i>Australian & New Zealand Journal of Obstetrics & Gynaecology</i> 2008;48(4):447.	Ineligible study design
Nohira T, Osakabe Y, Suda S, et al. Successful management by recombinant activated factor VII in a case of disseminated intravascular coagulopathy caused by obstetric hemorrhage. <i>Journal of Obstetrics & Gynaecology Research</i> 2008;34(4 Pt 2):623-630.	Ineligible study design
Nold J, Hargens L, Hagen E, et al. The use of recombinant factor VIIa (rFVIIa) to control bleeding in a neonate with disseminated intravascular coagulation and liver failure. <i>Blood</i> 2003;102(11):101b-102b.	Ineligible study design
Nonthasoot B, Nivatvongs S. Multiple doses of recombinant factor VIIa in orthotopic liver transplantation: a case report. <i>Transplant Proc</i> 2003;35(1):427-428.	Small sample size
Novak V, Mitov L, Rancić Z, et al. The use of recombinant activated factor VII in traumatic intracranial haemorrhage. <i>Srpski Arhiv Za Celokupno Lekarstvo</i> 2008;136 Suppl 3: 193-198.	Foreign language
NovoSeven for massive, uncontrollable, life-threatening haemorrhage in non-haemophiliacs - Early Warning on New Health Technology. Copenhagen: Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) 2003;2(1).	Ineligible study design
NovoSeven for non-hemophilia hemostasis. <i>Medical Letter on Drugs & Therapeutics</i> 2004;46(1181):33-34.	Ineligible study design
O'Connell KA, Wood JJ, Wise RP, et al. Thromboembolic adverse events after use of recombinant human coagulation factor VIIa. <i>JAMA</i> 2006;295(3):293-298.	Data combined for multiple conditions
O'Connell NM, Perry DJ, Hodgson AJ, et al. Recombinant FVIIa in the management of uncontrolled hemorrhage. <i>Transfusion</i> 2003;43(12):1711-1716.	Data combined for multiple conditions
O'Connor JV, Stein DM, Dutton RP, et al. Traumatic hemoptysis treated with recombinant human factor VIIa. <i>Ann Thorac Surg</i> 2006;81(4):1485-1487.	Small sample size
Odeyemi IA, Friederich PW, Levi M. Economic impact of recombinant activated factor VII in the control of bleeds associated with abdominal prostatectomy. <i>Journal of Medical Economics</i> 7:107-115.	Ineligible study design
Odeyemi IAO, Friederich PW, Levi M. Economic impact of recombinant activated factor VII in control of bleeds associated with abdominal prostatectomy. <i>J Med Econ</i> 2004;7:107-115.	Ineligible study design
Oh JJ, Akers WS, Lewis D, et al. Recombinant factor VIIa for refractory bleeding after cardiac surgery secondary to anticoagulation with the direct thrombin inhibitor lepirudin. <i>Pharmacotherapy</i> 2006;26(4):569-577.	Small sample size
O'Keeffe T, Refaai M, Tchorz K, et al. A massive transfusion protocol to decrease blood component use and costs. <i>Archives of Surgery</i> 2008 143(7):686-690; discussion 690-681.	No usable data
Olomu N, Kulkarni R, Manco-Johnson M. Treatment of severe pulmonary hemorrhage with activated recombinant factor VII (rFVIIa) in very low birth weight infants. <i>J Perinatol</i> 2002;22(8):672-674.	Ineligible study design

Excluded article	Reason for exclusion
Olomu N, Kulkarni R, Mano-Johnson M. Treatment of intrapulmonary hemorrhage with activated recombinant factor VII (rFVIIa) in very low birth weight (VLBW) infants on mechanical ventilation in a community level III neonatal intensive care unit (NICU). <i>Blood</i> 2001;98(11 Part 1):262a-263a.	Ineligible study design
O'Neill PA, Bluth M, Gloster ES, et al. Successful use of recombinant activated factor VII for trauma-associated hemorrhage in a patient without preexisting coagulopathy. <i>Journal of Trauma-Injury Infection & Critical Care</i> 2002;52(2):400-405.	Small sample size
Overdevest GM, Heetveld MJ. Open pelvic fractures: experience with recombinant factor VIIa, degloving and bowel injury. <i>Injury</i> 2007;38(3):384-391.	Small sample size
Owen PS, Golightly LK, MacLaren R, et al. Formulary management of recombinant factor VIIa at an academic medical center. <i>Annals of Pharmacotherapy</i> 2008;42(6):771-776.	Ineligible study design
Ozcelik T, Ozkocaman V, Ozkalemkas F, et al. Use of recombinant activated factor VII in a patient with severe thrombocytopenia due to myelodysplastic syndrome with uncontrolled gastrointestinal bleeding. <i>Blood Coagul Fibrinolysis</i> 2007;18(4):385-386.	Ineligible study design
Ozier Y, Klinck JR. Anesthetic management of hepatic transplantation. <i>Curr Opin Anaesthesiol</i> 2008;21(3):391-400.	Ineligible study design
Ozier Y, Schlumberger S. Pharmacological approaches to reducing blood loss and transfusions in the surgical patient. <i>Canadian Journal of Anaesthesia</i> 2006;53(6 Suppl):S21-S29.	Ineligible study design
Page MJ, Key NS, Rockwood T. Patient/caregiver assessment of convenience in the use of recombinant activated factor VII (rVIIa; NovoSeven) in home therapy. <i>Blood Coagul Fibrinolysis</i> 2000;11 Suppl 1:S51-S52.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Palacios Jaraquemada JM. Real efficacy of factor VIIa in the treatment of the postpartum hemorrhage. <i>Acta Obstet Gynecol Scand</i> 2005;84(11):1130; author reply 1131.	Ineligible study design
Palomino MA, Chaparro MJ, de Elvira MJ, et al. Recombinant activated factor VII in the management of massive obstetric bleeding. <i>Blood Coagul Fibrinolysis</i> 2006;17(3):226-227.	Ineligible study design
Panek G, Pawel D, Bidzinski M, et al. Successful use of activated recombinant factor FVIIa in the management of intra abdominal haemorrhage after cytoreductive surgery for advanced carcinoma of the ovary - a case report. <i>Nowotwory</i> 2002;53(4):308-311.	Ineligible study design
Pang G, Donaldson A. Probable right atrial thrombus immediately after recombinant activated factor VII administration. <i>British Journal of Anaesthesia</i> 2007;99(2):221-225.	Small sample size
Panya A, Jackson G, Wingmore T, et al. Management of surgery-associated bleeding in cancer patients. <i>Current Anaesthesia & Critical Care</i> 2008;19:59-69.	Ineligible study design
Papatheodoridis GV, Chung S, Keshav S, et al. Correction of both prothrombin time and primary haemostasis by recombinant factor VII during therapeutic alcohol injection of hepatocellular cancer in liver cirrhosis. <i>J Hepatol</i> 1999;31(4):747-750.	Ineligible study design
Pape H-C. Recombinant factor viia for life-threatening hemorrhage in trauma patients: review of the literature. <i>European Journal of Trauma</i> 2006;32(5):439-448.	Ineligible study design
Papia G, Klein D, Lindsay TF. Intensive care of the patient following open abdominal aortic surgery. <i>Curr Opin Crit Care</i> 2006;12(4):340-345.	Ineligible study design
Pardo M, Bartolome J, Carreno V, et al. Benefit of rFVIIa administration for cirrhotic patients undergoing surgery. <i>World J Surg</i> 2003;27(6):758-759.	Ineligible study design
Pardo Sanchez M, Nebreda JB, Carreno Garcia V. Recombinant activated factor VII prevents bleeding during a surgical procedure in a patient with uncontrollable rectal hemorrhage. <i>American Journal of Gastroenterology</i> 2002;97(5):1266-1267.	Ineligible study design
Park P, Fewel ME, Garton HJ, et al. Recombinant activated factor VII for the rapid correction of coagulopathy in nonhemophilic neurosurgical patients. <i>Neurosurgery</i> 2003;53(1):34-38; discussion 38-39.	Ineligible study design
Parker PJ, Adams SA, Williams D, et al. Forward surgery on Operation Telic--Iraq 2003. <i>Journal of the Royal Army Medical Corps</i> 2005;151(3):186-191.	Small sample size
Paschold JC, Macik BG. Recombinant activated factor VII for correction of the coagulopathy in a patient with cirrhosis requiring surgical drainage of a large epidural abscess. <i>Blood</i> . 2001;98(11 Part 2):76b.	Ineligible study design
Pastores SM, Papadopoulos E, Voigt L, et al. Diffuse alveolar hemorrhage after allogeneic hematopoietic stem-cell transplantation: Treatment with recombinant factor VIIa. <i>Chest</i> 2003;124(6):2400-2403.	Ineligible study design
Patanwala AE, Patanwala AE. Factor VIIa (recombinant) for acute traumatic hemorrhage. <i>American Journal of Health-System Pharmacy</i> 2008;65(17):1616-1623.	Ineligible study design

Excluded article	Reason for exclusion
Paterson NA. Validation of a theoretically derived model for the management of massive blood loss in pediatric patients. <i>Paediatric Anaesthesia</i> 2009;19(5):535-540.	Ineligible study design
Pattaras JG, Ogan K, Martinez E, et al. Endourological management of urolithiasis in hepatically compromised patients. <i>Journal of Urology</i> 2008;179(3):976-980.	Ineligible study design
Pavese P, Bonadona A, Beaubien J, et al. FVIIa corrects the coagulopathy of fulminant hepatic failure but may be associated with thrombosis: a report of four cases. <i>Can J Anaesth</i> 2005;52(1):26-29.	Small sample size
Payne EM, Brett SJ, Laffan MA. Efficacy of recombinant activated factor VII in unselected patients with uncontrolled haemorrhage: a single centre experience. <i>Blood Coagulation & Fibrinolysis</i> 2006;17(5):397-402.	Data combined for multiple conditions
Pejin D, Popovic S, Gebauer E, et al. The treatment of the life-threatening bleeding in haemophiliacs and in patients with acute leukaemia. Our experience. <i>Blood Reviews</i> 2007;21(Suppl 1):S100-S101.	Not on rFVIIa
Peon M-C. The evidence for the use of recombinant human activated factor VII in the treatment of bleeding patients with quantitative and qualitative platelet disorders. <i>Transfusion Medicine Reviews</i> 2007;21(3):223-236.	Ineligible study design
Pepas LP, Arif-Adib M, Kadir RA. Factor VIIa in puerperal hemorrhage with disseminated intravascular coagulation. <i>Obstet Gynecol</i> 2006;108(3 Pt 2):757-761.	Ineligible study design
Pepas LP, Arif-Adib M, Kadir RA. Factor VIIa in puerperal hemorrhage with disseminated intravascular coagulation. <i>Obstetrics & Gynecology</i> 2006;108(3 Part 2):757-761.	Ineligible study design
Pepe PE, Dutton RP, Fowler RL. Preoperative resuscitation of the trauma patient. <i>Current Opinion in Anaesthesiology</i> 2008;21(2):216-221.	Ineligible study design
Pepion C, Becq MC, Jacob L. Deep vein thrombosis after recombinant factor VIIa infusion to control severe recurrent postoperative bleeding. <i>Anesthesiology</i> 2006;104(4):892-893.	Ineligible study design
Perel P, Roberts I, Shakur H, et al. Haemostatic drugs for acute traumatic brain injury. <i>Cochrane Database of Systematic Reviews</i> 2009(3).	Ineligible study design
Perkins JG, Schreiber MA, Wade CE, et al. Early versus late recombinant factor VIIa in combat trauma patients requiring massive transfusion. <i>Journal of Trauma-Injury Infection & Critical Care</i> 2007;62(5):1095-1099; discussion 1099-1101.	Duplicate
Persson E. Variants of recombinant factor VIIa with increased intrinsic activity. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):89-92.	Not on rFVIIa
Pettersson M, Fischler B, Petrini P, et al. Recombinant FVIIa in children with liver disease. <i>Thrombosis Research</i> 2005;116(3):185-197.	Ineligible study design
Pfau G, Schilling T, Kozian A, et al. A single dose of recombinant activated factor VII (NovoSeven (R)) did not impair the function of the coronary artery bypass grafts - Successful treatment of critical bleeding after cardiac surgery in two cases. <i>Transfusion Medicine and Hemotherapy</i> 2007;34(3):204-207.	Small sample size
Pfliegler GP, Kovacs E, Nemeth H, et al. Oral anticoagulant induced angiosarcomatosis and disseminated intravascular coagulation. <i>Blood</i> 2007;110(11 Part 2):54B.	Ineligible study design
Phelan JT, II, Broder J, Kouides PA. Near-fatal uterine hemorrhage during induction chemotherapy for acute myeloid leukemia: A case report of bilateral uterine artery embolization. <i>American Journal of Hematology</i> 2004;77(2):151-155.	Ineligible study design
Philipson MR, Parker PJ. Damage Control Orthopaedics. <i>Trauma</i> 2007;9:245-254.	Ineligible study design
Piggott KD, Riedel PA, Baron HI. Multifocal lymphoendotheliomatosis with thrombocytopenia: a rare cause of gastrointestinal bleeding in the newborn period. <i>Pediatrics</i> 2006;117(4):e810-e813.	Ineligible study design
Plaat F. Recombinant factor VIIa should be used in massive obstetric haemorrhage. <i>Int J Obstet Anesth</i> 2007;16(4):354-357.	Ineligible study design
Planinsic RM, Testa G, Emre S, et al. Safety and efficacy of single bolus dose of recombinant factor VIIa in patients undergoing orthotopic liver transplantation: A randomized multi-center study. <i>Hepatology</i> 2002;36(4 Part 2):660A.	Duplicate
Planinsic RM. Use of recombinant factor VIIa (rFVIIa) in liver transportation [4]. <i>Liver Transplantation</i> 2006;12(7):1178-1179.	Ineligible study design
Plews DE, Thomas AE. Novel uses of recombinant factor VIIa. <i>Blood</i> . 1999;94(10 Suppl 1 Part 2):83b.	Ineligible study design
Poon MC, d'Oiron R. Recombinant activated factor VII (NovoSeven) treatment of platelet-related bleeding disorders. International Registry on Recombinant Factor VIIa and Congenital Platelet Disorders Group. <i>Blood Coagul Fibrinolysis</i> 2000;11 Suppl 1:S55-S68.	Ineligible study design

Excluded article	Reason for exclusion
Poovalingam V, Kenoyer DG, Mahomed R, et al. Superwarfarin poisoning: A report of 4 cases. <i>SAMJ (South African Medical Journal)</i> . 2002;92(11):874-876.	Not on rFVIIa
Popovic L, Peklic M, Kern J. Croatian experience in treatment with recombinant activated factor VII in pediatric liver transplantations. <i>Paediatr Croat</i> 2006;50:127-129.	Small sample size
Porte RJ, Caldwell SH. The role of recombinant factor VIIa in liver transplantation [comment]. <i>Liver Transplantation</i> 2005;11(8):872-874.	Ineligible study design
Porte RJ, Leebeek FWG. Pharmacological strategies to decrease transfusion requirements in patients undergoing surgery. <i>Drugs</i> 2002;62(15):2193-2211.	Ineligible study design
Potapov EV, Pasic M, Bauer M, et al. Activated recombinant factor VII for control of diffuse bleeding after implantation of ventricular assist device. <i>Annals of Thoracic Surgery</i> 2002;74(6):2182-2183.	Small sample size
Powner DJ, Hartwell EA, Hoots WK. Counteracting the effects of anticoagulants and antiplatelet agents during neurosurgical emergencies [see comment]. <i>Neurosurgery</i> 2005;57(5):823-831; discussion 823-831.	Ineligible study design
Prasad K. It is premature to use recombinant activated coagulation factor VIIa in intracerebral hemorrhage. <i>Annals of Indian Academy of Neurology</i> 2007;10(1).	Ineligible study design
Pratt EL, Tarantino MD. The cost of bridging protocols for anticoagulation in children enduring surgery. <i>Pediatric Research</i> 2002;51(4 Part 2):260A.	Ineligible study design
Presciutti M. Nursing priorities in caring for patients with intracerebral hemorrhage. <i>Journal of Neuroscience Nursing</i> 38(4 Suppl):296-269.	Ineligible study design
Prescott LM. Highlights of the American Stroke Association's 29th International Stroke Conference. <i>P&T</i> 2004;29(3):192-194.	Small sample size
Price G, Kaplan J, Skowronski G. Use of recombinant factor VIIa to treat life-threatening non-surgical bleeding in a post-partum patient. <i>Br J Anaesth</i> 2004;93(2):298-300.	Ineligible study design
Proceedings of the 6th Novo Nordisk Symposium on Treatment of Bleeding and Thrombotic Disorders. Copenhagen, Denmark, May 3-4, 2001. <i>Seminars in Hematology</i> 2001;38(4 Suppl 12):1-50.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Prondzinski MvD, Barthels M, Czwalianna A, et al. Stability of recombinant factor VIIa concentrate (rFVIIa) and its suitability for continuous infusion. <i>Annals of Hematology</i> 1999;78(Suppl 1):A46.	Animal or in-vitro study
Prosper SC, Goudge CS, Lupo VR. Recombinant factor VIIa to successfully manage disseminated intravascular coagulation from amniotic fluid embolism. <i>Obstet Gynecol</i> 2007;109(2 Pt 2):524-525.	Ineligible study design
Puetz J, Darling G, Brabec P, et al. The risk of thrombotic events in neonates treated with recombinant factor VIIa. <i>Blood</i> 2007;110(11 Part 1):938A.	Other: unpublished data
Pugh R, Wenstone R, Goh N. Recombinant activated factor VIIa (rFVIIa) in intractable haemorrhage: use of a clinical scoring system [comment] [erratum appears in <i>Vox Sang</i> 2006 Jul;91(1):91 Note: Wenstone R [corrected to Wenstone R]]. <i>Vox Sanguinis</i> 2006;90(4):331; author reply 332.	Ineligible study design
Pugh R, Wenstone R. Predicting response to recombinant factor VIIa in non-haemophiliac patients with severe haemorrhage [comment]. <i>British Journal of Anaesthesia</i> 2007;98(5):690; author reply 690-691.	Ineligible study design
Pugh RJ, Wenstone R, Martlew VJ, et al. Use of recombinant factor VIIa for major haemorrhage. <i>Eur J Anaesthesiol</i> 2005;22(7):548-550.	Small sample size
Punzalan RC, Ghanayem NS, Gill JC, et al. Off-label use of recombinant activated factor VII (rFVIIa) in children. <i>Blood</i> 2003;102(11):137b.	Small sample size
Pusateri AE, Park MS. Mechanistic implications for the use and monitoring of recombinant activated factor VII in trauma. <i>Critical Care (London, England)</i> 2005;9 Suppl 5:S15-S24.	Ineligible study design
Pychynska-Pokorska M, Moll JJ, et al. The use of recombinant coagulation factor VIIa in uncontrolled postoperative bleeding in children undergoing cardiac surgery with cardiopulmonary bypass [see comment]. <i>Pediatric Critical Care Medicine</i> 2004;5(3):246-250.	Small sample size
Pyrasopoulos N, Chalasani N, Balart L, et al. Recombinant factor VIIa is safe in patients with liver disease undergoing laparoscopic liver biopsy. <i>Hepatology</i> 2001;34(4 Pt 2):187A.	Duplicate
Pyrasopoulos N, Chalasani N, Balart L, et al. Recombinant factor VIIa safe in patients with liver disease undergoing laparoscopic liver biopsy [abstract]. <i>Hepatology</i> 2001;34(4).	Duplicate
Quan DJ, Bass NM, Hirose R. The effect of recombinant factor VIIa and fresh frozen plasma on the INR in patients with acute and chronic liver failure. <i>Hepatology</i> 2003;38(4 Suppl 1):550A.	Ineligible study design

Excluded article	Reason for exclusion
Quan DJ, Chee N, Bass N. Low dose recombinant factor VIIa improves the INR in patients with liver failure. <i>Pharmacotherapy</i> 2005;25(10):1449.	No eligible outcomes
Quillen K, Hirsch E, Bauza G. Efficacy of low-dose recombinant activated factor VII (rFVIIa) in massively transfused trauma patients with coagulopathy. <i>Blood</i> 2005;106(11 Part 1):279A.	Small sample size
Quinn TJ, Lees KR. European Stroke Conference, Glasgow, UK, May 29-June 1, 2007. <i>Int J Stroke</i> 2007;2(4):297-298.	Ineligible study design
Raghavendran K, Pryhuber GS, Chess PR, et al. Pharmacotherapy of acute lung injury and acute respiratory distress syndrome. <i>Current Medicinal Chemistry</i> 2008;15(19):1911-1924.	Not on rFVIIa
Rahman IA, Hoth T, Doughty H, et al. Thoraco-abdominal aneurysm repair in a Jehovah's Witness: maximising blood conservation. <i>Perfusion</i> 2007;22(5):363-364.	Ineligible study design
Raingard E, Allorent S, Treilhaud M, et al. Off-license use of activated recombinant factor VII in refractory bleeding in pulmonary transplantation. <i>Journal de Pharmacie Clinique</i> 2006;25(4):237-243.	Ineligible study design
Raj R. An approach to a child with recurrent bleeding. <i>Indian Journal of Practical Pediatrics</i> 2003;5(1):21.	Unable to obtain publication
Ramsey EZ, Smith KM, Flynn JD. Treatment of perioperative blood loss. <i>Orthopedics</i> 2006;29(9):770-772.	Ineligible study design
Ramsey G. Treating coagulopathy in liver disease with plasma transfusions or recombinant factor VIIa: an evidence-based review. <i>Best Pract Res Clin Haematol</i> 2006;19(1):113-126.	Ineligible study design
Ranucci M, Isgro G, Soro G, et al. Efficacy and safety of recombinant activated factor vii in major surgical procedures: systematic review and meta-analysis of randomized clinical trials. <i>Archives of Surgery</i> 2008;143(3):296-304; discussion 304.	Ineligible study design
Ranucci M, Isgro G, Soro G, et al. Efficacy and safety of recombinant activated factor vii in major surgical procedures: systematic review and meta-analysis of randomized clinical trials [see comment]. <i>Archives of Surgery</i> 2008;143(3):296-304; discussion 304.	Ineligible study design
Ranucci M, Isgro G. Recombinant activated factor VII in cardiac surgery. <i>European Journal of Anaesthesiology</i> 2007;24(Suppl 40):83-88.	Ineligible study design
Raobaikady R, Grounds RM. The role of activated recombinant factor VII (rFVIIa) in acute severe bleeding. <i>Clinical Intensive Care</i> 2004;15(4):115-117.	Ineligible study design
Raobaikady R, Redman J, Ball J, et al. The use of activated recombinant coagulation factor VII in patients undergoing major reconstruction surgery for traumatic fracture pelvis or pelvis and acetabulum: a doubleblind, randomised, placebo-controlled trial. <i>Critical Care</i> 2005;9(Suppl 1):338.	Duplicate
Rapaport SI. Coagulation problems in liver disease. <i>Blood Coagulation and Fibrinolysis</i> 2000;11(Suppl 1):S69-S74.	Ineligible study design
Ratko TA, Cummings JP, Matuszewski KA. Off-label use of recombinant activated factor VII (NovoSeven®). <i>P&T</i> 2004;29(11):712-720.	Ineligible study design
Raux M, Chiche L, Vanhille E, et al. Recombinant activated factor vii to control massive post operative bleeding after septic aortobifemoral grafting. <i>European Journal of Anaesthesiology</i> 2005;22(10):805-807.	Ineligible study design
Raynaud L, Grasser L, Vichard A, et al. Recombinant activated factor VII and management of severe bleeding: Present indications; Interest for the health service of the armies in combat areas? <i>Medecine et Armees</i> 2007;35(1):67-74.	Ineligible study design
Razon Y, Erez E, Vidne B, et al. Recombinant factor VIIa (NovoSeven) as a hemostatic agent after surgery for congenital heart disease. <i>Paediatr Anaesth</i> 2005;15(3):235-240.	Small sample size
Reade MC, Toyoda YN, Murray HN. Failure of an Abiomed left ventricular assist device in association with factor VIIa administration. <i>Minerva Anestesiologica</i> 2008;74(4):145-148.	Small sample size
Recombinant factor VIIa (NovoSeven) for life-threatening surgical and traumatic bleeding in non-haemophiliacs - horizon scanning review. Birmingham: National Horizon Scanning Centre (NHSC) 2003:4.	Ineligible study design
Recombinant factor VIIa (NovoSeven) for life-threatening surgical and traumatic bleeding in non-haemophiliacs - horizon scanning review. Birmingham: National Horizon Scanning Centre (NHSC) 2004.	Ineligible study design
Recombinant factor VIIa (NovoSeven) for prevention and treatment of bleeding in patients with underlying disease - horizon scanning review. Birmingham: National Horizon Scanning Centre (NHSC) 2003:7.	Ineligible study design

Excluded article	Reason for exclusion
Recombinant factor VIIa (NovoSeven) in intracerebral haemorrhage (ICH) - horizon scanning review. Birmingham: National Horizon Scanning Centre (NHSC) 2004:5.	Ineligible study design
Recombinant factor VIIa in haemostasis - horizon scanning review. Birmingham: National Horizon Scanning Centre (NHSC) 2002.	Ineligible study design
Redaelli R, Caimi TM, Somaini G, et al. Feasibility and safety of recombinant factor VIIa (rFVIIa) administered by continuous infusion (C.I.) through a central vein catheter (CVC). <i>Blood</i> 1998;92(10 Suppl 1 Part 1-2):137B.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Refaai MA, Tchorz K, Forestner J, et al. The use of recombinant FVIIa in a structured massive transfusion protocol: A novel approach. <i>Blood</i> 2006;108(11 Part 2):115B.	Ineligible study design
Reiter PD, Valuck RJ, Taylor RS. Evaluation of off-label recombinant activated factor VII for multiple indications in children. <i>Clinical & Applied Thrombosis/Hemostasis</i> 2007;13(3):233-240.	Small sample size
Revesz T, Arets B, Bierings M, et al. Recombinant factor VIIa in severe uremic bleeding. <i>Thromb Haemost</i> 1998;80(2):353.	Ineligible study design
Reyes G, Carrasco N, Munoz T, et al. Management of massive pulmonary embolism using recombinant activated factor VII. <i>European Journal of Cardio-Thoracic Surgery</i> 2008;33(6):1144-1145.	Small sample size
Rezende SM, Pimentel BD, Araujo JPB. Knocking down the price of factor concentrates in Brazil. <i>Haemophilia</i> 2005;11(3):290-291.	Ineligible study design
Riazi S, Karkouti K, Heggie J. Case report: management of life-threatening oropharyngeal bleeding with recombinant factor VIIa. <i>Canadian Journal of Anaesthesia</i> 2006;53(9):881-884.	Small sample size
Richards M, Kinsey S, Stringer M. Recombinant FVIIa for surgical bleeding in childhood. <i>British Journal of Haematology</i> 2003;121(Suppl 1):36.	Ineligible study design
Rincon F, Buitrago MM, Mayer SA. Hemostatic therapy for intracerebral hemorrhage. <i>Current Atherosclerosis Reports</i> 2006;8(4):304-309.	Ineligible study design
Rizoli SB, Boffard KD, Riou B, et al. Recombinant activated factor VII as an adjunctive therapy for bleeding control in severe trauma patients with coagulopathy: subgroup analysis from two randomized trials. <i>Crit Care</i> 2006;10(6):R178.	Duplicate
Rizoli SB, Chughtai T. The emerging role of recombinant activated Factor VII (rFVIIa) in the treatment of blunt traumatic haemorrhage. <i>Expert Opin Biol Ther</i> 2006;6(1):73-81.	Ineligible study design
Rizvi AZ, Slone DS, Schrelber MA. Modulation of the coagulation cascade using recombinant factor VIIa and activated protein C in a severely injured trauma patient. <i>European Journal of Trauma</i> . 2006;32(4):399-403.	Small sample size
Roberts HR, Monroe 3rd DM, Hoffman M. Safety profile of recombinant factor VIIa. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):101-108.	Ineligible study design
Roberts HR, Monroe DM, Key NS. Clinical role of recombinant factor VIIa in bleeding disorders; 2008. (Tanaka K, Davie EW, Ikeda Y, et al., eds. <i>Recent Advances in Thrombosis and Hemostasis</i> 2008).	Ineligible study design
Roberts HR, Monroe DM, White GC. The use of recombinant factor VIIa in the treatment of bleeding disorders. <i>Blood</i> 2004;104(13):3858-3864.	Ineligible study design
Roberts HR. Recombinant factor VIIa (NovoSeven(R)) and the safety of treatment. <i>Seminars in Hematology</i> 2001;38(4 Suppl 12):48-50.	Ineligible study design
Roberts HR. Recombinant factor VIIa: a general hemostatic agent? Yes [see comment]. <i>Journal of Thrombosis & Haemostasis</i> 2004;2(10):1691-1694.	Ineligible study design
Roberts HR. Recombinant factor VIIa: how safe is the stuff? <i>Can J Anaesth</i> 2005;52(1):8-11.	Ineligible study design
Robertson JD. Prevention of intraventricular haemorrhage: a role for recombinant activated factor VII? <i>Journal of Paediatrics & Child Health</i> 2006;42(6):325-331.	Ineligible study design
Rodriguez V, Reed AM, Kuntz NL, et al. Antiphospholipid syndrome with catastrophic bleeding and recurrent ischemic strokes as initial presentation of systemic lupus erythematosus. <i>Journal of Pediatric Hematology/Oncology</i> 2005;27(7):403-407.	Ineligible study design
Roitberg B. Research news and notes. <i>Surgical Neurology</i> 2005;63(6):495-496.	Ineligible study design
Romagnoli S, Bevilacqua S, Gelsomino S, et al. Small-dose recombinant activated factor VII (NovoSeven) in cardiac surgery. <i>Anesth Analg</i> 2006;102(5):1320-1326.	Duplicate
Romero Castro R, Barroso Relinque N, Caunedo Alvarez A, et al. Use of recombinant factor VII in hepatology. <i>Rev Esp Enferm Dig</i> 2001;93(10):664-668.	Ineligible study design

Excluded article	Reason for exclusion
Romero JR, Sakai O, Rice MB, et al. Intracranial hemorrhage sparing meningioma in an anticoagulated patient. <i>J Neuroimaging</i> 2007;17(3):246-250.	Small sample size
Romero R, Pellicer F, Jimenez M, et al. Recombinant activated factor VII (rFVIIa) in the treatment of four cases of severe hemorrhage from portal hypertension (PH). <i>Gastroenterology</i> 2002;122(4 Suppl 1):A79.	Ineligible study design
Romero R, Pellicer F, Jimenez M, et al. Recombinant activated factor VII (RFVIIA) in the treatment of seven cases of severe and active bleeding esophageal varices. <i>Digestive Disease Week Abstracts and Itinerary Planner 2003:Abstract No. M1784.</i>	Ineligible study design
Romero-Castro R, Jimenez-Saenz M, Pellicer-Bautista F, et al. Recombinant-activated factor VII as hemostatic therapy in eight cases of severe hemorrhage from esophageal varices. <i>Clin Gastroenterol Hepatol</i> 2004;2(1):78-84.	Ineligible study design
Romero-Castro R, Jimenez-Saenz M, Pellicer-Bautista F, et al. Refractory bleeding after endoscopic sphincterotomy: A new indication for recombinant factor VII therapy? <i>American Journal of Gastroenterology</i> 2004;99(10):2063-2065.	Ineligible study design
Romero-Castro R, Jimenez-Saenz M, Pellicer-Bautista FJ, et al. A case of bleeding gastric varices treated with recombinant factor VII. <i>Rev Esp Enferm Dig</i> 2001;93(10):675-676.	Ineligible study design
Romero-Castro R, Pellicer-Bautista F, Jimenez-Saenz M, et al. Recombinant activated factor VII (rFVIIa) in the treatment of 13 patients with severe and active bleeding esophageal varices. <i>Gastroenterology</i> 2004;126(4 Suppl 2):A386.	Ineligible study design
Rose L. Recombinant factor VIIa: review of current "off license" indications and implications for practice. <i>AACN Advanced Critical Care</i> 2007;18(2):141-148.	Ineligible study design
Rosovsky RP, Crowther MA, Rosovsky RP, et al. What Is the Evidence for the Off-label Use of Recombinant Factor VIIa (rFVIIa) in the Acute Reversal of Warfarin? <i>Hematology</i> 2008:36-38.	Ineligible study design
Ross KB. Emergent interventions for intracerebral hemorrhage. <i>Journal of Medical Speech-Language Pathology</i> . 2005;13(4):ix-xii.	Ineligible study design
Rossaint R, Duranteau J, Stahel PF, et al. Nonsurgical treatment of major bleeding. <i>Anesthesiology Clinics</i> ;25(1):35-48.	Ineligible study design
Rossaint R, Riou B, Boffard K, et al. A randomised, placebo-controlled, double-blind study to investigate the efficacy and safety of rFVIIa as adjunctive therapy for control of bleeding in patients with severe blunt trauma: a reanalysis following the exclusion of early (< 48 hours) deaths. <i>Critical Care</i> 2005;9(Suppl 1):337.	Duplicate
Rott H, Trobisch H, Kretschmar E. Use of recombinant factor VIIa, Novo Seven, in the management of acute haemorrhage. <i>Current Opinion in Anaesthesiology</i> 2004;17(2):159-163.	Ineligible study design
Rudisill CN, Hockman RH, Degregory KA, et al. Implementing guidelines for the institutional use of factor VIIa (recombinant): a multidisciplinary solution. <i>American Journal of Health-System Pharmacy</i> 2006;63(17):1641-1646.	Ineligible study design
Rumyantsev AG, Babkova NV, Chernov VM. Clinical application of recombinant activated coagulation factor VII. <i>Gematologiya i Transfuziologiya</i> 2002;47(5):36-41.	Ineligible study design
Sachs B, Delacy D, Green J, et al. Recombinant activated factor VII in spinal surgery. <i>Spine</i> 2007;32(21):2285-2293.	Duplicate
Saeed G, Ganster G, Friedel N, et al. Was systemic venous thrombosis really due to the administration of recombinant factor VIIa? or was it possibly a manifestation of Lemierre syndrome? <i>Texas Heart Institute Journal</i> 2008;35(3):373-374; author reply 374-376.	Ineligible study design
Sahni R, Weinberger J. Management of intracerebral hemorrhage. <i>Vasc Health Risk Manag</i> 2007;3(5):701-709.	Ineligible study design
Saito Y, Healy B, Kaufman RM, et al. Off-label use of recombinant FVIIa: Clinical characteristics that may influence outcomes. <i>Blood</i> 2005;106(11 Part 1):130A.	Data combined for multiple conditions
Sajdak S, Moszynski R, Opala T. Bleeding from endometrial and vaginal malignant tumors treated with activated recombinant factor VII. <i>Eur J Gynaecol Oncol</i> 2002;23(4):325-326.	Ineligible study design
Salama A, Rieke M, Kiesewetter H, et al. Experiences with recombinant FVIIa in the emergency treatment of patients with autoimmune thrombocytopenia: a review of the literature. <i>Annals of Hematology</i> . 2009;88(1):11-15.	Ineligible study design
Salek SZ, Sokolic V, Viskovic T, et al. Successful use of recombinant factor VIIa for massive bleeding after caesarean section due to HELLP syndrome. <i>Acta Haematologica (Basel)</i> 2002;108(3):162-163.	Ineligible study design

Excluded article	Reason for exclusion
Sallah AS, Wan J, Sigounas GD, et al. Recombinant activated factor VII can control the bleeding manifestations of disseminated intravascular coagulation in patients with cancer. <i>Blood</i> 2002;100(11):Abstract No. 3873.	Ineligible study design
Sallah S, Husain A, Nguyen NP. Recombinant activated factor VII in patients with cancer and hemorrhagic disseminated intravascular coagulation. <i>Blood Coagulation & Fibrinolysis</i> 2004;15(7):577-582.	Ineligible study design
Sallah S, Isaksen M, Seremetis S, et al. Comparative thrombotic event incidence after infusion of recombinant factor VIIa vs. factor VIII inhibitor bypass activity--a rebuttal. <i>J Thromb Haemost</i> 2005;3(4):820-822; author reply 822.	Ineligible study design
Samama CM. Preemptive use of recombinant activated factor VII: many questions but few answers. <i>Canadian Journal of Anesthesia</i> 2006;53(4):336-338.	Ineligible study design
Sanchez MP, Nebreda JB, Garcia VC. Recombinant activated factor VII prevents bleeding during a surgical procedure in a patient with uncontrollable rectal hemorrhage. <i>Am J Gastroenterol</i> 2002;97(5):1266-1267.	Ineligible study design
Sanchis Cervera J, Andres Blasco CJ, Mena-Duran AV. Treatment of acute bleeding with recombinant factor VIIa in a patient with IgA deficit receiving anticoagulant therapy. <i>Acta Haematol</i> 2003;110(1):51-52.	Ineligible study design
Sander M, von Heymann C, Kox WJ, et al. Recombinant factor VIIa for excessive bleeding after thrombectomy prior to kidney transplantation. <i>Transplantation</i> 2004;77(12):1912-1913.	Ineligible study design
Sapsford W. The potential use of recombinant activated factor VII in trauma and surgery. <i>Scandinavian Journal of Surgery: SJS</i> 2004;93(1):17-23.	Ineligible study design
Sattin JA, Zivin JA. Emerging therapies for acute ischemic stroke. <i>American Journal of Therapeutics</i> 2007;14(3):291-298.	Ineligible study design
Saxon BR, Shanks D, Jory CB, et al. Effective prophylaxis with daily recombinant factor VIIa (rFVIIa-Novoseven) in a child with high titre inhibitors and a target joint. <i>Thromb Haemost</i> 2001;86(4):1126-1127.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Saxonhouse MA, Sola MC. Platelet function in term and preterm neonates. <i>Clinics in Perinatology</i> 2004;31(1):15-28.	Ineligible study design
Scarpelini S, Rizoli S. Recombinant factor VIIa and the surgical patient. <i>Current Opinion in Critical Care</i> . 2006;12(4):351-356.	Ineligible study design
Schlifka B. Lessons learned perspective from OIF: A neurosurgical. <i>Journal of Trauma Injury Infection and Critical Care</i> . 2007;62(6 Suppl S):S103-S104.	Ineligible study design
Schmid S, Friesenecker B, Lorenz I, et al. Administration of recombinant activated factor VII (NovoSeven) in three cases of uncontrolled bleeding caused by disseminated intravascular coagulopathy. <i>Clinical & Applied Thrombosis/Hemostasis</i> 2007;13(3):313-317.	Ineligible study design
Schneck MJ, Biller J. Hemorrhagic stroke in the tropics. <i>Semin Neurol</i> 2005;25(3):300-306.	Ineligible study design
Schreiber MA. Coagulopathy in the trauma patient. <i>Current Opinion in Critical Care</i> 2005;11(6):590-597.	Ineligible study design
Schreiber MA. Damage control surgery. <i>Critical Care Clinics</i> 2004;20(1):101-118.	Ineligible study design
Schulman S, Bech Jensen M, Varon D, et al. Feasibility of using recombinant factor VIIa in continuous infusion. <i>Thromb Haemost</i> 1996;75(3):432-436.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Schulman S, Jensen MB, Varon D, et al. Feasibility of using recombinant factor VIIa in continuous infusion. <i>Blood</i> 1995;86(10 Suppl 1):191A.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Schulman S, Lindstedt M, Alberts KA, et al. Recombinant factor VIIa in multiple surgery. <i>Thromb Haemost</i> 1994;71(1):154.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Schulman S. Safety, efficacy and lessons from continuous infusion with rFVIIa. rFVIIa-CI Group. <i>Haemophilia</i> 1998;4(4):564-567.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)

Excluded article	Reason for exclusion
Schuster R, Lee SJ, Rink D. Treatment of bleeding in severe hemorrhagic pancreatitis with recombinant factor VIIa. <i>Am Surg</i> 2003;69(11):1017-1018.	Ineligible study design
Scully MF. First Eastern Canadian Symposium on Hemostasis. <i>Transfusion and Apheresis Science</i> 2008;38:5-7.	Ineligible study design
Searle E, Pavord S, Alfirevic Z. Recombinant factor VIIa and other pro-haemostatic therapies in primary postpartum haemorrhage. <i>Best Practice & Research in Clinical Obstetrics & Gynaecology</i> 2008;22(6):1075-1088.	Ineligible study design
Seeburger J, Groesdonk H, Borger MA, et al. Quadruple valve replacement for acute endocarditis. <i>Journal of Thoracic and Cardiovascular Surgery</i> 2009;137(6):1564-1565	Ineligible study design
Segal S, Shemesh IY, Blumental R, et al. The use of recombinant factor VIIa in severe postpartum hemorrhage. <i>Acta Obstet Gynecol Scand.</i> 2004;83(8):771-772.	Ineligible study design
Segal S, Shemesh IY, Blumenthal R, et al. Treatment of obstetric hemorrhage with recombinant activated factor VII (rFVIIa). <i>Arch Gynecol Obstet</i> 2003;268(4):266-267.	Ineligible study design
Selin S, Tejani A. Recombinant activated factor VII for bleeding in patients without inherited bleeding disorders. <i>Issues Emerg Health Technol</i> 2006(82):1-4.	Ineligible study design
Shah NL, Caldwell SH, Berg CL, et al. The role of anti-fibrinolytics, rFVIIa and other pro-coagulants: prophylactic versus rescue? <i>Clinics in Liver Disease</i> 2009;13(1):87-93.	Ineligible study design
Shalmi M, Aurup P. Off-label reports of new biologics: exciting new therapy or dubious research? Examples from recombinant activated factor VII.[comment]. <i>Journal of Intensive Care Medicine</i> 2006;21(4):247-248.	Ineligible study design
Shamsi T, Tufail M, Aftab M, et al. Role of recombinant activated factor VII in securing haemostatic failure in gun shot trauma. <i>J Pak Med Assoc</i> 2006;56(5):238-241.	Small sample size
Shamsi TS, Hossain N, Soomro N, et al. Use of recombinant factor VIIa for massive postpartum haemorrhage: case series and review of literature. <i>J Pak Med Assoc</i> 2005;55(11):512-515.	Ineligible study design
Shander A, Javidroozi M. Invited commentary. <i>Ann Thorac Surg</i> 2008;85(3):844.	Ineligible study design
Shander A, Moskowitz D, Rijhwani TS. The safety and efficacy of "bloodless" cardiac surgery. <i>Semin Cardiothorac Vasc Anesth</i> 2005;9(1):53-63.	Ineligible study design
Shapiro AD. Recombinant Factor VIIa: A Viewpoint by Amy D. Shapiro. <i>Biodrugs</i> 1999;12(1):78-79.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Sheares KKK, Mahadeva R. Recombinant factor VIIa and intravenous immunoglobulin therapy for diffuse alveolar haemorrhage: A cautionary tale? <i>Respiratory Medicine Extra</i> 2005;1:120-123.	Ineligible study design
Sheth KN. Recombinant activated factor VII for acute intracerebral hemorrhage. <i>N Engl J Med</i> 2005;352(20):2133-2134; author reply 2133-2134.	Ineligible study design
Shopnick RI. Reversal of warfarin using recombinant factor VIIa prior to invasive procedures. <i>Blood</i> 2001;98(11 Part 2):99b.	Ineligible study design
Siegel LJ, Gerigk L, Tuettenberg J, et al. Cerebral sinus thrombosis in a trauma patient after recombinant activated factor VII infusion. <i>Anesthesiology</i> 2004;100(2):441-443.	Small sample size
Silva MA, Muralidharan V, Mirza DF. The management of coagulopathy and blood loss in liver surgery. <i>Seminars in Hematology.</i> 2004;41(1 Suppl 1):132-139.	Ineligible study design
Silva Z-S. Rapid Reversal of anticoagulant bleeding- rfvii a an option? <i>Journal of Postgraduate Medicine</i> 2007;53(1):3-4.	Ineligible study design
Silver DA, D'Ambra MN. Recombinant activated factor VII in cardiac surgery--will we ever know for sure? <i>Crit Care Med</i> 2007;35(7):1782-1783.	Ineligible study design
Skolnick BE, Brun NC, Kruse P, et al. Safety and laboratory results for recombinant activated coagulation factor VII in patients with acute intracerebral hemorrhage. <i>Blood</i> 2003;102(11 Part 1).	Duplicate
Slappendel R, Huvers FC, Benraad B, et al. Use of recombinant factor VIIa (NovoSeven(R)) to reduce postoperative bleeding after total hip arthroplasty in a patient with cirrhosis and thrombocytopenia. <i>Anesthesiology (Hagerstown)</i> 2002;96(6):1525-1527.	Ineligible study design
Slappendel R, Huvers FC, Benraad B, et al. Use of recombinant factor VIIa (NovoSeven) to reduce postoperative bleeding after total hip arthroplasty in a patient with cirrhosis and thrombocytopenia. <i>Anesthesiology</i> 2002;96(6):1525-1527.	Ineligible study design
Smythe MA, Dager WE, Patel NM. Managing complications of anticoagulant therapy. <i>Journal of Pharmacy Practice</i> 2004;17(5):327.	Ineligible study design

Excluded article	Reason for exclusion
Sniecinski RM, Chen EP, Levy JH, et al. Coagulopathy after cardiopulmonary bypass in Jehovah's Witness patients: management of two cases using fractionated components and factor VIIa. <i>Anesth Analg</i> 2007;104(4):763-765.	Small sample size
Snorr J. Risk, benefits and complications of epidural steroid injections: a case report. <i>AANA</i> 2007;75(3):183-188.	Ineligible study design
Sobel BE, Schneider DJ. Platelet function, coagulopathy, and impaired fibrinolysis in diabetes. <i>Cardiology Clinics</i> 2004;22(4):511-V.	Not on rFVIIa
Sobieszczyk S, Breborowicz GH, Platcanov V, et al. Recombinant factor VIIa in the management of postpartum bleeds: an audit of clinical use. <i>Acta Obstet Gynecol Scand</i> 2006;85(10):1239-1247.	Ineligible study design
Soghier LM, Brion LP, Weinberg G, et al. Use of recombinant activated factor VII for refractory hemorrhage in a neonate. <i>Blood</i> 2003;102(11):100b.	Ineligible study design
Sokolic V, Bukovic D, Fures R, et al. Recombinant factor VIIa (rFVIIa) is effective at massive bleeding after caesarean section--a case report. <i>Coll Antropol</i> 2002;26 Suppl:155-157.	Ineligible study design
Sorensen B, Fenger-Eriksen C, Ingerslev J. Recombinant factor VIIa fails to correct coagulopathy induced by haemodilution with colloid. <i>Br J Anaesth</i> 2005;94(6):862-863.	Animal or in-vitro study
Sorensen B, Ingerslev J. Thromboelastography and recombinant factor VIIa: Hemophilia and beyond. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):140-144.	Ineligible study design
Sorensen B, Johansen P, Nielsen GL, et al. Reversal of the International Normalized Ratio with recombinant activated factor VII in central nervous system bleeding during warfarin thromboprophylaxis: clinical and biochemical aspects. <i>Blood Coagulation & Fibrinolysis</i> 2003;14(5):469-477.	Small sample size
Soudry E, Stein M. Prehospital management of uncontrolled bleeding in trauma patients: nearing the light at the end of the tunnel. <i>Israel Medical Association Journal: IMAJ</i> 2004;6(8):485-489.	Ineligible study design
Sousa C, Pedroto I, Campos M, et al. Spontaneous hematoma of the colon. <i>Endoscopy</i> 2000;32(12):S74.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Spahr JE, Maul JS, Rodgers GM. Superwarfarin poisoning and review of: A report of two cases the literature. <i>American Journal of Hematology</i> . 2007;82(7):656-660.	Ineligible study design
Spalding GJ, Hartrumpf M, Sierig T, et al. Cost reduction of perioperative coagulation management in cardiac surgery: value of "bedside" thrombelastography (ROTEM). <i>European Journal of Cardio-Thoracic Surgery</i> 2007;31(6):1052-1057.	Ineligible study design
Spalding GJ, Hartrumpf M, Sierig T, et al. Cost reduction of perioperative coagulation management in cardiac surgery: value of 'bedside' thrombelastography (ROTEM). <i>European Journal of Cardio-Thoracic Surgery</i> ;31(6):1052-1057.	Ineligible study design
Special report: recombinant activated factor VII for uncontrolled bleeding in non-hemophiliac patients. <i>Technol Eval Cent Asses Program Exec Summ</i> 2006;21(10):1-2.	Ineligible study design
Spivey M, Parr MJA. Therapeutic approaches in trauma-induced coagulopathy. <i>Minerva Anestesiologica</i> 2005;71(6):281-289.	Ineligible study design
Squizzato A, Ageno W. Recombinant activated factor VII as a general haemostatic agent: evidence-based efficacy and safety. <i>Curr Drug Saf</i> 2007;2(2):155-161.	Ineligible study design
Stachnik JM, Gabay MP. Continuous infusion of coagulation factor products. <i>Annals of Pharmacotherapy</i> 2002;36(5):882-891.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Stanworth S, Birchall J, Doree C, et al. Recombinant factor VIIa for the prevention and treatment of bleeding in patients without haemophilia [Systematic Review]. <i>Cochrane Database of Systematic Reviews</i> 2008(2).	Ineligible study design
Stanworth SJ, Birchall J, Doree CJ, et al. Recombinant factor VIIa for the prevention and treatment of bleeding in patients without haemophilia. <i>Cochrane Database Syst Rev</i> 2007(2):CD005011.	Ineligible study design
Stein DM, Dutton RP, Hess JR, et al. Low-dose recombinant factor VIIa for trauma patients with coagulopathy. <i>Injury</i> 2008;39(9):1054-1061.	Duplicate
Stein DM, Dutton RP, Kramer ME, et al. Reversal of coagulopathy in critically ill patients with traumatic brain injury: recombinant factor VIIa is more cost-effective than plasma. <i>Journal of Trauma-Injury Infection & Critical Care</i> 2009;66(1):63-72; discussion 73-65.	Duplicate

Excluded article	Reason for exclusion
Stein DM, Dutton RP, O'Connor J, et al. Determinants of futility of administration of recombinant factor VIIa in trauma. <i>J Trauma</i> 2005;59(3):609-615.	Duplicate
Stein DM, Dutton RP. Uses of recombinant factor VIIa in trauma. <i>Curr Opin Crit Care</i> 2004;10(6):520-528.	Ineligible study design
Stein SC, Smith DH. Coagulopathy in traumatic brain injury. <i>Neurocritical Care</i> 2004;1(4):479-488.	Ineligible study design
Steiner ME, Key NS, Levy JH. Activated recombinant factor VII in cardiac surgery. <i>Current Opinion in Anaesthesiology</i> 2005;18(1):89-92.	Ineligible study design
Steiner T, Diener HC, Unterberg A, et al. Spontaneous intracerebral haemorrhages - What is new? <i>Aktuelle Neurologie</i> 2006;33(5):251-256.	Ineligible study design
Steiner T, Diringer MN, Schneider D, et al. Dynamics of intraventricular hemorrhage in patients with spontaneous intracerebral hemorrhage: risk factors, clinical impact, and effect of hemostatic therapy with recombinant activated factor VII. <i>Neurosurgery</i> 2006;59(4):767-773; discussion 773-774.	Duplicate
Steiner T, Juettler E, Ringleb P. Acute stroke therapy. Current developments. <i>Nervenarzt</i> 2007;78(10):1147-1154.	Ineligible study design
Steiner T, Mayer S, Brun N. Safety and preliminary efficacy of activated recombinant factor VII (novoseven) in acute intracerebral haemorrhage. <i>Cerebrovascular Diseases</i> 2003;16(Suppl 4).	Duplicate
Steiner T, Rosand J, Diringer M. Intracerebral hemorrhage associated with oral anticoagulant therapy: current practices and unresolved questions. <i>Stroke</i> 2006;37(1):256-262.	Ineligible study design
Steiner T, Schneider D, Mayer S, et al. Impact of intraventricular haemorrhage on outcomes after recombinant activated Factor VII treatment in patients with acute intracerebral haemorrhage. <i>Cerebrovascular Diseases</i> 2005;19(Suppl 2).	Duplicate
Steiner T, Schneider D, Mayer SA, et al. Impact of intraventricular haemorrhage on outcomes following recombinant activated factor VII treatment in patients with acute intracerebral haemorrhage. <i>Journal of the Neurological Sciences</i> 2005;238(Suppl 1).	Duplicate
Stepinska J, Banaszewski M, Konopka A, et al. Activated recombinant factor VII (rFVIIa) in bleeding management after therapy with IIb/IIIa-inhibitor tirofiban. <i>Thrombosis and Haemostasis</i> 2002;87(2):355-356.	Ineligible study design
Sternbach M, Dragomir A, Crowther MA, et al. Unexpected harmful side effects triggered by immune modulation. <i>Blood</i> 2006;108(11 Part 2):80B.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Stocker CF, Shekerdeman LS. Recent developments in the perioperative management of the paediatric cardiac patient. <i>Current Opinion in Anaesthesiology</i> 2006;19(4):375-381.	Ineligible study design
Stratmann G, deSilva AM, Tseng EE, et al. Reversal of direct thrombin inhibition after cardiopulmonary bypass in a patient with heparin-induced thrombocytopenia. <i>Anesthesia & Analgesia</i> 2004;98(6):1635-1639.	Small sample size
Stratmann G, Russell IA, Merrick SH. Use of recombinant factor VIIa as a rescue treatment for intractable bleeding following repeat aortic arch repair. <i>Annals of Thoracic Surgery</i> 2003;76(6):2094-2097.	Small sample size
Strauss RA, Gloster ES. Off-Label Use of Recombinant Activated Factor VII (rFVIIa) for Enucleation Following Eye Trauma. <i>Blood</i> 2002;100(11):Abstract No. 3910.	Small sample size
Streif W, Borum Andreassen R, Paes B, et al. Influence of activated factor VII concentrates on thrombin generation in full-term and preterm neonates. <i>Blood Coagul Fibrinolysis</i> 2000;11 Suppl 1:S133-S134.	Animal or in-vitro study
Stromqvist BN. The use of recombinant factor VIIa for severe intractable bleeding during spine surgery - Point of view. <i>Spine</i> 2004;29(12):1388.	Ineligible study design
Subramaniam S, Demchuk A, Watson TWJ, et al. Unexpected post hemorrhagic hydrocephalus in patients treated with recombinant activated factor VII (rFVIIa): A cause for concern? <i>Neurology</i> 2006;66(5 Suppl 2):303.	Small sample size
Subramaniam S, Demchuk AM, Watson T, et al. Unexpected posthemorrhagic hydrocephalus in patients treated with rFVIIa [see comment]. <i>Neurology</i> 2006;67(6):1096.	Small sample size
Sugg RM, Gonzales NR, Matherne DE, et al. Myocardial injury in patients with intracerebral hemorrhage treated with recombinant factor VIIa. <i>Neurology</i> 2006;67(6):1053-1055.	Duplicate

Excluded article	Reason for exclusion
Sugg RM, Gonzales NR, Matherne DE, et al. Myocardial injury in patients with intracerebral hemorrhage treated with recombinant factor VIIa [see comment]. <i>Neurology</i> 2006;67(6):1053-1055.	Duplicate
Sumann G, Kampfl A, Wenzel V, et al. Early intensive care unit intervention for trauma care: what alters the outcome? <i>Current Opinion in Critical Care</i> 2002;8(6):587-592.	Ineligible study design
Surbek D, Huber A, Alberio L, et al. The role of recombinant factor VIIa in the treatment of severe post partum hemorrhage: Can fertility be preserved? <i>American Journal of Obstetrics and Gynecology</i> 2006;195(6 Suppl S):S92.	Ineligible study design
Surudo T, Wojcicki M, Milkiewicz P, et al. Rapid correction of prothrombin time after low-dose recombinant factor VIIA in patients undergoing orthotopic liver transplantation. <i>Transplant Proc</i> 2003;35(6):2323-2325.	Small sample size
Sutherland GR, Auer RN. Primary intracerebral hemorrhage. <i>Journal of Clinical Neuroscience</i> 2006;13(5):511-517.	Ineligible study design
Svartholm E, Annerhagen V, Lanne T. Treatment of bleeding in severe necrotizing pancreatitis with recombinant factor VIIa. <i>Anesthesiology</i> 2002;96(6):1528.	Ineligible study design
Sykora M, Diedler J, Steiner T. Repetitive asystole in right insular haemorrhage. <i>J Neurol Neurosurg Psychiatry</i> 2007;78(11):1282-1283.	Small sample size
Szabo T, Ali S, Camporesi EM. Intraoperative recombinant activated factor VII for emergent epidural hematoma evacuation. <i>Anesthesia & Analgesia</i> 99(2):595-597.	Small sample size
Takabe K, Holman PR, Herbst KD, et al. Successful perioperative management of factor X deficiency associated with primary amyloidosis. <i>J Gastrointest Surg</i> 2004;8(3):358-362.	Other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)
Taketomi T, Szlam F, Levy JH, et al. Warfarin reversal with prothrombin complex concentrate confers better antifibrinolytic activity compared with recombinant activated factor VII. <i>Blood Coagulation & Fibrinolysis</i> 2008;19(1):106-108.	Animal or in-vitro study
Taketomi T, Szlam F, Levy JH, et al. Warfarin reversal with prothrombin complex concentrate confers better antifibrinolytic activity compared with recombinant activated factor VII. <i>Blood Coagulation & Fibrinolysis</i> 2008;19(1):106-108.	Animal or in-vitro study
Talkad A, Mathews M, Honings D, et al. Reversal of warfarin-induced anticoagulation with factor VIIa prior to rt-PA in acute stroke. <i>Neurology</i> 2005;64(8):1480-1481.	Ineligible study design
Tanaka KA, Waly AA, Cooper WA, et al. Treatment of excessive bleeding in Jehovah's Witness patients after cardiac surgery with recombinant factor VIIa (NovoSeven). <i>Anesthesiology</i> 2003;98(6):1513-1515.	Small sample size
Tancabelic J, Haun SE. Management of coagulopathy with recombinant factor VIIa in a neonate with echovirus type 7. <i>Pediatr Blood Cancer</i> 2004;43(2):170-176.	Ineligible study design
Tanchev S, Platikanov V, Karadimov D. Administration of recombinant factor VIIa for the management of massive bleeding due to uterine atonia in the post-placental period. <i>Acta Obstet Gynecol Scand</i> 2005;84(4):402-403.	Ineligible study design
Tanos M, Dunning J. Is recombinant activated factor VII useful for intractable bleeding after cardiac surgery? <i>Interactive Cardiovascular & Thoracic Surgery</i> 2006;5(4):493-498.	Ineligible study design
Tawfick WA, Tawfik S, Hynes N, et al. Critical bleeding in vascular surgery: expanding the indication of recombinant activated factor VII. <i>Vascular</i> 2006;14(1):32-37.	Ineligible study design
Teitel J, Poon MC. The safety of recombinant factor VIIa: a rebuttal [comment]. <i>Journal of Thrombosis & Haemostasis</i> 2004;2(11):2078; author reply 2079.	Ineligible study design
Teitel JM. Unexpected bleeding disorders: Algorithm for approach to therapy. <i>Clinical & Laboratory Haematology</i> 2000;22 Suppl 1:26-29; discussion 30-32.	Ineligible study design
Thabut D, de Franchis R, Bendtsen F, et al. Efficacy of activated recombinant factor VII (RFVIIA; NOVOSEVEN) in cirrhotic patients with upper gastrointestinal bleeding: A randomised placebo-controlled double-blind multicenter trial [abstract]. <i>Journal of Hepatology</i> 2003;38(Suppl 2).	Duplicate
Thakar MS, Liedel JL, Rubin CM, et al. FVIIa for peri-operative bleeding in the PICU and NICU. <i>Pediatric Research</i> 2004;55(4 Suppl S, Part 2):307A-308A.	Data combined for multiple conditions
Thomas GO, Dutton RP, Hemlock B, et al. Thromboembolic complications associated with factor VIIa administration. <i>J Trauma</i> 2007;62(3):564-569.	Duplicate
Thompson AR. When all else fails to stop massive bleeding from trauma [comment]. <i>Journal of Thrombosis & Haemostasis</i> 2005;3(4):638-639.	Ineligible study design
Thompson KM, Gerlach SY, Jorn HKS, et al. Files JA. Advances in the care of patients with intracerebral hemorrhage. <i>Mayo Clinic Proceedings</i> 2007;82(8):987-990.	Ineligible study design

Excluded article	Reason for exclusion
Thompson RC. Intracerebral hemorrhage: the least treatable form of stroke [comment]. <i>Southern Medical Journal</i> 2005;98(8):760.	Ineligible study design
Tien H, Nascimento Jr B, Callum J, et al. An approach to transfusion and hemorrhage in trauma: current perspectives on restrictive transfusion strategies. <i>Canadian Journal of Surgery</i> 2007;50(3):202-209.	Ineligible study design
Tien HC, Gough MR, Farrell R, et al. Successful use of recombinant activated coagulation factor VII in a patient with massive hemoptysis from a penetrating thoracic injury. <i>Ann Thorac Surg</i> 2007;84(4):1373-1374.	Small sample size
Tieu BH, Holcomb JB, Schreiber MA. Coagulopathy: its pathophysiology and treatment in the injured patient. <i>World Journal of Surgery</i> . 2007;31(5):1055-1064.	Ineligible study design
Tinmouth AT, McIntyre LA, Fowler RA, et al. Blood conservation strategies to reduce the need for red blood cell transfusion in critically ill patients. <i>CMAJ Canadian Medical Association Journal</i> 2008;178(1):49-57.	Ineligible study design
Tinmouth AT, McIntyre LA, Fowler RA. Blood conservation strategies to reduce the need for red blood cell transfusion in critically ill patients. <i>CMAJ Canadian Medical Association Journal</i> 2008;178(1):49-57.	Ineligible study design
Tobias JD, Berkenbosch JW, Muruve NA, et al. Correction of a coagulopathy using recombinant factor VII before removal of an intra-aortic balloon pump. <i>J Cardiothorac Vasc Anesth</i> 2002;16(5):612-614.	Ineligible study design
Tobias JD, Berkenbosch JW, Russo P. Recombinant factor VIIa to treat bleeding after cardiac surgery in an infant. <i>Pediatr Crit Care Med</i> 2003;4(1):49-51.	Small sample size
Tobias JD, Berkenbosch JW. Synthetic factor VIIa concentrate to treat coagulopathy and gastrointestinal bleeding in an infant with end-stage liver disease. <i>Clin Pediatr (Phila)</i> 2002;41(8):613-616.	Ineligible study design
Tobias JD, Groeper K, Berkenbosch JW. Preliminary experience with the use of recombinant factor VIIa to treat coagulation disturbances in pediatric patients. <i>South Med J</i> 2003;96(1):12-16.	Small sample size
Tobias JD. Synthetic factor VIIa to treat dilutional coagulopathy during posterior spinal fusion in two children. <i>Anesthesiology</i> 2002;96(6):1522-1525.	Ineligible study design
Toffolon EP. Correcting PT with factor 7 may not improve clotting. <i>Gastroenterology</i> 1998;115(3):800.	Ineligible study design
Tofil NM, Winkler MK, Watts RG, et al. The use of recombinant factor VIIa in a patient with Noonan syndrome and life-threatening bleeding [see comment]. <i>Pediatric Critical Care Medicine</i> 2005;6(3):352-354.	Other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)
Tong MZ, Chin-Yee I, Eckert K, et al. Efficacy and questionable safety of recombinant activated factor VII in intractable bleeding following cardiac surgery. <i>Canadian Journal of Cardiology</i> 2007;23(Suppl C):291C.	Other: unpublished data
Towfighi A, Greenberg SM, Rosand J. Treatment and prevention of primary intracerebral hemorrhage. <i>Seminars in Neurology</i> 2005;25(4):445-452.	Ineligible study design
Tran KM, Flake AW, Kalawadia NV, et al. Emergent excision of a prenatally diagnosed sacrococcygeal teratoma. <i>Paediatr Anaesth</i> 2008;18(5):431-434.	Ineligible study design
Traynor K. Budget-busting drug gets institutional oversight. <i>American Journal of Health-System Pharmacy</i> 61(9):866.	Ineligible study design
Trowbridge CC, Stammers AH, Ciccarelli N, et al. Dose titration of recombinant factor VIIa using thromboelastograph monitoring in a child with hemophilia and high titer inhibitors to factor VIII: a case report and brief review. <i>Journal of Extra-Corporeal Technology</i> 2006;38(3):254-259.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Tsochatzis E, Papatheodoridis GV, Elefsiniotis I, et al. Prophylactic and therapeutic use of recombinant activated factor VII in patients with cirrhosis and coagulation impairment. <i>Dig Liver Dis</i> 2007;39(5):490-494.	Ineligible study design
Tuhim S. Intracerebral hemorrhage--improving outcome by reducing volume? [comment]. <i>New England Journal of Medicine</i> 2008;358(20):2174-2176.	Ineligible study design
Ucar C, Caliskan U. Successful treatment of acute lymphoblastic leukemia with L-asparaginase-induced intracranial hemorrhage to activated recombinant factor VIIa in a child. <i>Pediatric Hematology & Oncology</i> 2006;23(4):339-345.	Small sample size

Excluded article	Reason for exclusion
Udvardy M, Telek B, Mezey G, et al. Successful control of massive coumarol-induced acute upper gastrointestinal bleeding and correction of prothrombin time by recombinant active factor VII (Eptacog-alpha, NovoSeven) in a patient with a prosthetic aortic valve and two malignancies (chronic lymphoid leukaemia and lung cancer). <i>Blood Coagulation & Fibrinolysis</i> 2004;15(3):265-267.	Ineligible study design
Udy A, Vaghela M, Lawton G, et al. The use of recombinant activated factor VII in the control of haemorrhage following blunt pelvic trauma [see comment]. <i>Anaesthesia</i> 2005;60(6):613-616.	Small sample size
Uhlmann EJ, Eby CS. Recombinant activated factor VII for non-hemophiliac bleeding patients. <i>Curr Opin Hematol</i> 2004;11(3):198-204.	Ineligible study design
Uhrig L, Blanot S, Baugnon T, et al. Use of recombinant activated factor VII in intractable bleeding during pediatric neurosurgical procedures. <i>Pediatr Crit Care Med</i> 2007;8(6):576-579.	Small sample size
Vaishnav A. International Stroke Conference 2006 16-18 February 2006, Kissimmee, Florida, CA USA. <i>Expert Rev Neurother</i> 2006;6(5):629-630.	Ineligible study design
Valadka AB, Robertson CS. Surgery of cerebral trauma and associated critical care. <i>Neurosurgery (Hagerstown)</i> . 2007;61(1 Suppl S):203-220.	Ineligible study design
van de Garde EM, Bras LJ, Heijmen RH, et al. Low-dose recombinant factor VIIa in the management of uncontrolled postoperative hemorrhage in cardiac surgery patients. <i>J Cardiothorac Vasc Anesth</i> 2006;20(4):573-575.	Small sample size
van de Minkelis JL, Steenvoorde P, Baranski AG. Liver rupture in a patient with HELLP syndrome successfully treated with extensive surgery combined with recombinant factor VIIa. <i>Acta Chir Belg</i> . 2006;106(5):602-604.	Ineligible study design
Van De Velde M. Massive obstetric hemorrhage due to abnormal placentation: uterotonic drugs, cell salvage and activated recombinant factor seven. <i>Acta Anaesthesiologica Belgica</i> 2008;59(3):197-200.	Ineligible study design
Van de Velde M. Recombinant factor VIIa should be used in massive obstetric haemorrhage. <i>Int J Obstet Anesth</i> 2007;16(4):357-359.	Ineligible study design
van der Linden J. Novel antithrombotic agents and the risk of bleeding. <i>Transfusion</i> 2008;48(1 Suppl):47S-50S.	Ineligible study design
Van Der Schueren B, Hammer F, Verschuren F, et al. Angiographic documentation of the efficacy of recombinant activated factor VII (NovoSeven) to control diffuse bleeding in major trauma. <i>Thromb Haemost</i> 2005;94(6):1327-1328.	Small sample size
van 't Veer C, Mann KG. The regulation of the factor VII-dependent coagulation pathway: Rationale for the effectiveness of recombinant factor VIIa in refractory bleeding disorders. <i>Seminars in Thrombosis and Hemostasis</i> 2000;26(4):367-372.	Animal or in-vitro study
Van Thiel DH, Anantharaju A, Mindikoglu AL, et al. Modulation of endothelial cell inflammatory integrins and stress markers with rh-factor VIIa in patients with advanced chronic hepatitis C. <i>J Viral Hepat</i> 2003;10(4):310-317.	In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
Van Thiel DH, Farr DE, Mindikoglu AL, et al. Recombinant human factor VIIa-induced alterations in tissue factor and thrombomodulin in patients with advanced liver cirrhosis. <i>Journal of Gastroenterology & Hepatology</i> 2005;20(6):882-889.	No eligible outcomes
Van Thiel DH, George M, Anantharaju A, et al. Acute consumption of plasma tissue factor and thrombomodulin with the administration of recombinant human factor VIIa to individuals with advanced liver disease. <i>Gastroenterology</i> 2002;122(4 Suppl 1):A655.	Ineligible study design
van Veen EJW, Monteban-Kooistra WE, Meertens JHJM, et al. Recombinant human activated factor VII in postpartum hemorrhagic shock: the dark side. <i>Intensive Care Medicine</i> 2008;34(1):211-212.	Ineligible study design
Vanek T, Straka Z, Hrabak J, et al. Use of recombinant activated factor VII in cardiac surgery for an effective treatment of severe intractable bleeding. <i>Jpn Heart J</i> 2004;45(5):855-860.	Small sample size
Vater Y, Levy A, Martay K, et al. Adjuvant drugs for end-stage liver failure and transplantation. <i>Medical Science Monitor</i> 2004;10(4):RA77-RA88.	Ineligible study design
Veldman A, Hoffman M, Ehrenforth S. New insights into the coagulation system and implications for new therapeutic options with recombinant factor VIIa. <i>Curr Med Chem</i> 2003;10(10):797-811.	Ineligible study design
Veldman A, Josef J, Fischer D, et al. A prospective pilot study of prophylactic treatment of preterm neonates with recombinant activated factor VII during the first 72 hours of life. <i>Pediatr Crit Care Med</i> 2006;7(1):34-39.	Small sample size

Excluded article	Reason for exclusion
Veldman A, Neuhaeuser C, Akintuerk H, et al. rFVIIa in the treatment of persistent hemorrhage in pediatric patients on ECMO following surgery for congenital heart disease. <i>Paediatr Anaesth</i> 2007;17(12):1176-1181.	Small sample size
Velik-Salchner C, Sergi C, Fries D, et al. Use of recombinant factor VIIa (Novoseven) in combination with other coagulation products led to a thrombotic occlusion of the truncus brachiocephalicus in a neonate supported by extracorporeal membrane oxygenation. <i>Anesth Analg</i> 2005;101(3):924.	Small sample size
Verre M, Bossio F, Mammone A, et al. Use of recombinant activated factor VII in a case of severe postpartum haemorrhage. <i>Minerva Ginecol</i> 2006;58(1):81-84.	Ineligible study design
Verrijckt A, Proulx F, Morneau S, et al. Activated recombinant factor VII for refractory bleeding during extracorporeal membrane oxygenation. <i>J Thorac Cardiovasc Surg</i> 2004;127(6):1812-1813.	Small sample size
Veshchev I, Elran H, Salame K. Recombinant coagulation factor VIIa for rapid preoperative correction of warfarin-related coagulopathy in patients with acute subdural hematoma. <i>Med Sci Monit</i> 2002;8(12):CS98-CS100.	Small sample size
Vick LR, Islam S. Recombinant factor VIIa as an adjunct in nonoperative management of solid organ injuries in children. <i>J Pediatr Surg</i> 2008;43(1):195-198; discussion 198-199.	Small sample size
Vidarsson B, Onundarson PT. Recombinant factor VIIa for bleeding in refractory thrombocytopenia. <i>Thromb Haemost</i> 2000;83(4):634-635.	Ineligible study design
Vidarsson B, Onundarson PT. Successful use of recombinant factor VIIa in a bleeding patient with refractory thrombocytopenia undergoing chemotherapy for acute leukemia. <i>Blood</i> 1999;94(10 Suppl 1 Part 2):239b.	Ineligible study design
Viles-Gonzalez JF, Gaztanaga J, Zafar UM, et al. Clinical and experimental experience with factor Xa inhibitors. <i>American Journal of Cardiovascular Drugs</i> 2004;4(6):379-384.	Not on rFVIIa
Vilstrup H, Markiewicz M, Biesma D, et al. Recombinant activated factor VII in an unselected series of cases with upper gastrointestinal bleeding. <i>Thrombosis Research</i> 2006;118(5):595-601.	Ineligible study design
Vincent JL, Rossaint R, Riou B, et al. Recommendations on the use of recombinant activated factor VII as an adjunctive treatment for massive bleeding. A European perspective. <i>Annales Francaises d'Anesthesie et de Reanimation</i> 2007;26(2):145-156.	Ineligible study design
Vincent J-L, Rossaint R, Riou B, et al. Recommendations on the use of recombinant activated factor VII as an adjunctive treatment for massive bleeding--a European perspective. <i>Critical Care (London, England)</i> 2006;10(4):R120.	Ineligible study design
Virchis A, Hughes C, Berney S. Severe gastrointestinal haemorrhage responding to recombinant factor VIIa in a Jehovah's Witness with refractory immune thrombocytopenia. <i>Hematol J</i> 2004;5(3):281-282.	Ineligible study design
Vlot AJ, Ton E, Mackaay AJ, et al. Treatment of a severely bleeding patient without preexisting coagulopathy with activated recombinant factor VII. <i>Am J Med</i> 2000;108(5):421-423.	Ineligible study design
Voils S. Pharmacologic interventions for the management of critical bleeding. <i>Pharmacotherapy</i> 2007;27(9 Pt 2):69S-84S.	Ineligible study design
Volk T, von Heymann C, Kox WJ. Recombinant activated factor VII and perioperative blood loss.[comment]. <i>Lancet</i> 2003;361(9370):1745; author reply 1745-1746.	Ineligible study design
von Heymann C, Hotz H, Konertz W, et al. Successful treatment of refractory bleeding with recombinant factor VIIa after redo coronary artery bypass graft surgery. <i>J Cardiothorac Vasc Anesth</i> 2002;16(5):615-616.	Small sample size
von Heymann C, Jonas S, Spies C, et al. Recombinant activated factor VIIa for the treatment of bleeding in major abdominal surgery including vascular and urological surgery: a review and meta-analysis of published data. <i>Critical Care (London, England)</i> 2008;12(1):R14.	Ineligible study design
von Heymann C, Schoenfeld H, Sander M, et al. Clopidogrel-related refractory bleeding after coronary artery bypass graft surgery: a rationale for the use of coagulation factor concentrates? <i>Heart Surg Forum</i> 2005;8(1):E39-E41.	Small sample size
von Heymann C, Ziemer S, Kox WJ, et al. Caveat against the use of feiba in combination with recombinant factor viia.[comment]. <i>Journal of Thoracic & Cardiovascular Surgery</i> 2003;126(5):1667-1668.	Ineligible study design
Vyas H, Kulkarni R, Guertin S, et al. Use of recombinant activated FVII (rFVIIa) for the treatment of uncontrolled bleeding episodes in pediatric patients in a community hospital. <i>Pediatric Research</i> 2004;55(4 Suppl S, Part 2):308A.	Small sample size

Excluded article	Reason for exclusion
Vyas H, Kulkarni R, Guertin S, John F. Recombinant activated FVII (rFVIIa) for the treatment of severe bleeding episodes in pediatric patients in a community hospital. <i>Blood</i> 2003;102(11):100b.	Small sample size
Waddington DP, McAuley FT, Hanley JP, et al. The use of recombinant factor viia in a Jehovah's witness with auto-immune thrombocytopenia and post-splenectomy haemorrhage. <i>Br J Haematol</i> 2002;119(1):286-288.	Ineligible study design
Wahed S, Karagounis AP, Niranjana G, et al. Successful graft patency after factor VIIa use for bleeding in coronary artery surgery: an unusual complication of a coronary artery bypass surgery. <i>Journal of Cardiac Surgery</i> 2007;22(5):424-427.	Small sample size
Wahlgren CM, Swedenborg J. The use of recombinant activated factor VII to control bleeding during repair of a suprarenal abdominal aortic aneurysm. <i>Eur J Vasc Endovasc Surg</i> 2003;26(2):221-222.	Ineligible study design
Walsham J, Fraser JF, Mullany D, et al. The use of recombinant activated factor VII for refractory bleeding post complex cardiothoracic surgery. <i>Anaesth Intensive Care</i> 2006;34(1):13-20.	Small sample size
Waner M. Novel hemostatic alternatives in reconstructive surgery. <i>Seminars in Hematology</i> 2004;41(1 Suppl 1):163-167.	Ineligible study design
Warkentin TE, Crowther MA. Reversing anticoagulants both old and new. <i>Canadian Journal of Anesthesia</i> 2002;49(6 Suppl):S11-S25.	Ineligible study design
Warkentin TE, Jay RM, Makris M, et al. Platelet-activating anti-platelet factor 4/polyanion antibodies without preceding heparin therapy: A transient autoimmune disorder resembling heparin-induced thrombocytopenia ("spontaneous HIT"). <i>Blood</i> 2006;108(11 Part 1):311A-312A.	Not on rFVIIa
Warren O, Mandal K, Hadjianastassiou V, et al. Recombinant activated factor VII in cardiac surgery: a systematic review. <i>Annals of Thoracic Surgery</i> 2007;83(2):707-714.	Ineligible study design
Warren OJ, Alcock EM, Choong AM, et al. Recombinant activated factor VII: a solution to refractory haemorrhage in vascular surgery? <i>Eur J Vasc Endovasc Surg</i> 2008;35(2):145-152.	Ineligible study design
Warren OJ, Darzi AW, Athanasiou T. Recombinant activated factor VII in cardiac surgery - first, do no harm. <i>Journal of Cardiothoracic Surgery</i> 2007;2:50.	Ineligible study design
Wartenberg KE, Mayer SA. Reducing the risk of ICH enlargement. <i>Journal of the Neurological Sciences</i> 2007;261(1-2):99-107.	Ineligible study design
Watson HG, Salamat AA, Tait J, et al. Successful treatment of life-threatening haemorrhage with rVIIa during autologous peripheral blood stem cell transplantation complicated by platelet refractoriness. <i>Blood</i> 2002;100(11):Abstract No. 3783.	Ineligible study design
Watts RG, Hilliard LM. Use of recombinant factor VIIa for uncontrolled bleeding in critically ill children with malignancy. <i>Blood</i> 2001;98(11 Part 2):85b-86b.	Ineligible study design
Weant KA, Flynn JF, Akers WS. Management of antiplatelet therapy for minimization of bleeding risk before cardiac surgery. <i>Pharmacotherapy</i> 2006;26(11):1616-1625.	Ineligible study design
Webert KE, Arnold DM, Carruthers J, et al. Utilization of recombinant activated factor VII in southern Ontario in 85 patients with and without haemophilia. <i>Haemophilia</i> 2007;13(5):518-526.	Data combined for multiple conditions
Webert KE, Blajchman MA. Randomized trials in patients with blunt and penetrating trauma [comment]. <i>Journal of Trauma-Injury Infection & Critical Care</i> 2006;60(1):242-243; author reply 243-244.	Ineligible study design
Wehbi MA, Obideen K, Martinez E, et al. Recombinant factor VIIa (rFVIIa) as a safe and effective therapeutic option for the correction of moderate to severe hepatic coagulopathy. <i>Hepatology</i> 2003;38(4 Suppl 1):482A.	Ineligible study design
Wei Y-F, Ho C-C, Lin M-T, et al. Successful treatment of intractable hemothorax with recombinant factor VIIa in a nonhemophilic patient. <i>Journal of the Formosan Medical Association</i> 2006;105(9):765-769.	Ineligible study design
Weinberger J. Recombinant activated factor VII for acute intracerebral hemorrhage. <i>Current Cardiology Reports</i> 2006;8(1):8.	Ineligible study design
Weiskopf RB. Intraoperative use of recombinant activated coagulation factor VII. <i>Anesthesiology</i> . 2002;96(6):1287-1289.	Ineligible study design
Weiskopf RB. Recombinant-activated coagulation factor VIIa (NovoSeven): current development. <i>Vox Sanguinis</i> 2007;92(4):281-288.	Ineligible study design
Weiskopf RB. The use of recombinant activated coagulation factor VII for spine surgery. <i>Eur Spine J</i> 2004;13 Suppl 1:S83-S88.	Ineligible study design

Excluded article	Reason for exclusion
Welsby IJ, Monroe DM, Lawson JH, et al. Recombinant activated factor VII and the anaesthetist. <i>Anaesthesia</i> 2005;60(12):1203-1212.	Ineligible study design
Welsby IJ, Ortel TL. Invited commentary. <i>Ann Thorac Surg</i> 2007;84(1):168-169.	Ineligible study design
Welsh A, McLintock C, Gatt S, et al. Guidelines for the use of recombinant activated factor VII in massive obstetric haemorrhage [see comment]. <i>Australian & New Zealand Journal of Obstetrics & Gynaecology</i> 2008;48(1):12-16.	Ineligible study design
Welsh A, McLintock C, Gatt S, et al. Guidelines for the use of recombinant activated factor VII in massive obstetric haemorrhage. <i>Australian & New Zealand Journal of Obstetrics & Gynaecology</i> 2008;48(1):12-16.	Ineligible study design
Wheater MJ, Mead GM, Bhandari S, et al. Recombinant factor VIIa in the management of pulmonary hemorrhage associated with metastatic choriocarcinoma. <i>J Clin Oncol</i> 2008;26(6):1008-1010.	Ineligible study design
White B, Martin M, Kelleher S, et al. Successful use of recombinant FVIIa (Novoseven) in the management of pulmonary haemorrhage secondary to Aspergillus infection in a patient with leukaemia and acquired FVII deficiency. <i>Br J Haematol</i> 1999;106(1):254-255.	Other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)
White B, McHale J, Ravi N, et al. Successful use of recombinant FVIIa (Novoseven) in the management of intractable post-surgical intra-abdominal haemorrhage. <i>Br J Haematol</i> 1999;107(3):677-678.	Ineligible study design
White CE, Schrank AE, Baskin TW, et al. Effects of recombinant activated factor VII in traumatic nonsurgical intracranial hemorrhage. <i>Curr Surg</i> 2006;63(5):310-317.	Small sample size
White II GC. Congenital and acquired platelet disorders: Current dilemmas and treatment strategies. <i>Seminars in Hematology</i> 2006;43(1 Suppl 1):S37-S41.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
White MC, Pryn SJ, Monk CR. Thrombogenic side-effects of recombinant factor VIIa after use in coronary artery bypass surgery. <i>Anaesth Intensive Care</i> 2006;34(5):664-667.	Small sample size
Whitlock R, Crowther MA, Ng HJ. Bleeding in cardiac surgery: its prevention and treatment—an evidence-based review. <i>Crit Care Clin</i> 2005;21(3):589-610.	Ineligible study design
Wiesenack C, Arlt M, Liebold A, et al. Successful use of one dose of recombinant factor VIIa to control severe bleeding after emergency aortic arch replacement in deep hypothermic circulatory arrest. <i>Journal of Thoracic & Cardiovascular Surgery</i> 2004;128(6):941-943.	Small sample size
Wijdicks EFM. Limiting cerebral hematoma expansion. <i>Reviews in Neurological Diseases</i> 2005;2(3):163-165.	Duplicate
Williams AP, Gettinger A. Transfusion therapy in the intensive care unit. <i>Current Opinion in Anaesthesiology</i> 2006;19(2):127-131.	Ineligible study design
Williams D, McCarthy R. Recombinant activated factor VII and perioperative blood loss [comment]. <i>Lancet</i> 2003;361(9370):1745; author reply 1745-1746.	Ineligible study design
Williams DJ, Thomas GO, Pambakian S, et al. First military use of activated Factor VII in an APC-III pelvic fracture. <i>Injury</i> 2005;36(3):395-399.	Small sample size
Wilson SJ, Bellamy MC, Giannoudis PV. The safety and efficacy of the administration of recombinant activated factor VII in major surgery and trauma patients. <i>Expert Opin Drug Saf</i> 2005;4(3):557-570.	Ineligible study design
Wittenstein B, Ng C, Ravn H, et al. Recombinant factor VII for severe bleeding during extracorporeal membrane oxygenation following open heart surgery. <i>Pediatr Crit Care Med</i> 2005;6(4):473-476.	Small sample size
Wojcicki M, Lubikowski J, Wrzesinski M, et al. Outcome of emergency liver transplantation including mortality on the waiting list: a single-center experience. <i>Transplantation Proceedings</i> 2007;39(9):2781-2784.	Small sample size
Wong WY, Huang WC, Miller R, et al. Clinical efficacy and recovery levels of recombinant FVIIa (NovoSeven) in the treatment of intracranial haemorrhage in severe neonatal FVII deficiency. <i>Haemophilia</i> 2000;6(1):50-54.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Woo YJ. Cardiac surgery in patients on antiplatelet and antithrombotic agents. <i>Semin Thorac Cardiovasc Surg</i> 2005;17(1):66-72.	Ineligible study design

Excluded article	Reason for exclusion
Wordliczek J, Serednicki W, Grabowska I, et al. A 43-year-old man was admitted to the hospital with the diagnosis of acute pancreatitis of 4 days' duration. <i>Pancreas</i> 2003;26(1):101-102.	Ineligible study design
Wrobel G, Dobaczewski G, Patkowski D, et al. Experiences with recombinant activated factor VII in the treatment of severe refractory thrombocytopenia. <i>Pediatr Blood Cancer</i> 2006;47(5 Suppl):729-730.	Ineligible study design
Wu JK, Keith RH, George SG. Use of recombinant activated factor VII (rFVIIa) for acute reversal of warfarin in a child. <i>Blood</i> 2002;100(11):Abstract No. 3964.	Ineligible study design
Xi G, Keep RF, Hoff JT. Mechanisms of brain injury after intracerebral haemorrhage. <i>Lancet Neurology</i> 2006;5(1):53-63.	Ineligible study design
Yadav SP, Chugh K, Gupta D, et al. Use of recombinant factor VIIa in children with uncontrolled bleeding - A single centre experience. <i>Blood</i> 2006;108(11 Part 2):94B-95B.	Ineligible study design
Yadav SP, Sharma SD, Kharya G, et al. Control of massive bleeding in dengue hemorrhagic fever with severe thrombocytopenia by use of KhamRho-IV Anti D (R). <i>Blood</i> 2007;110(11 Part 1):621A.	Ineligible study design
Yan Q, Chang AC. Pharmacologic therapy for postoperative bleeding in children after cardiac surgery: when will the bleeding stop?[comment]. <i>Pediatric Critical Care Medicine</i> 2004;5(3):297-298.	Ineligible study design
Yang L, Jankovic Z. Orthotopic liver transplantation in Jehovah's Witnesses. <i>Current Anaesthesia & Critical Care</i> 2008;19:31-41.	Ineligible study design
Yildirim H, Ucgun I, Yalcin AU, et al. Recombinant factor VIIa treatment for life-threatening haemoptysis. <i>Respirology</i> 2006;11(5):652-654.	Ineligible study design
Yildirim Z, Branda RF. Use of recombinant activated factor VII (rFVIIa) to correct coagulopathy due to congestive liver failure in preparation for surgery. <i>Blood</i> 2002;100(11):Abstract No. 3888.	Ineligible study design
Yilmaz D, Karapinar B, Balkan C, et al. Single-center experience: use of recombinant factor VIIa for acute life-threatening bleeding in children without congenital hemorrhagic disorder. <i>Pediatric Hematology & Oncology</i> 2008;25(4):301-311.	Small sample size
Yilmaz D, Karapinar B, Balkan C, et al. Single-center experience: Use of recombinant factor VIIa for acute life-threatening bleeding in children without congenital hemorrhagic disorder. <i>Pediatr Hematol Oncol</i> 2008;25(4):301-311.	Ineligible study design
You H, Al-Shahi R. Haemostatic drug therapies for acute primary intracerebral haemorrhage [Systematic Review]. <i>Cochrane Database of Systematic Reviews</i> 2008(2).	Ineligible study design
You H, Al-Shahi R. Haemostatic drug therapies for acute primary intracerebral haemorrhage. <i>Cochrane Database of Systematic Reviews</i> 2006;3:CD005951.	Ineligible study design
Young G, Lloyd S, Nugent DJ. Recombinant factor VIIa in patients with liver failure undergoing surgery. <i>Blood</i> 2000;96(11 Part 1):267a.	Ineligible study design
Young G, Nugent DJ. Prevention of bleeding complications in neonates with liver failure undergoing surgery using recombinant factor VIIa. <i>Hematology</i> 2001;6(5):341-346.	Ineligible study design
Yovtchev V, Gancheva S. The use of recombinant activated factor VII (rFVIIa) for patients with massive hemorrhage provoked by different cases. <i>Anaesthesiology and Intensive Care</i> 2006;33(2):13-16.	Unable to obtain publication
Yusim Y, Perel A, Berkenstadt H, et al. The use of recombinant factor VIIa (NovoSeven) for treatment of active or impending bleeding in brain injury: broadening the indications. <i>Journal of Clinical Anesthesia</i> 2006;18(7):545-551.	Small sample size
Zaaroor M, Soustiel JF, Brenner B, et al. Administration off label of recombinant factor-VIIa (rFVIIa) to patients with blunt or penetrating brain injury without coagulopathy. <i>Acta Neurochirurgica</i> 2008;150(7):663-668.	Small sample size
Zahuranec DB. The 2005 International Stroke Conference, New Orleans, Louisiana, February 2-4, 2005. <i>Journal of Neuro-Ophthalmology</i> 2005;25(2):150-151.	Ineligible study design
Zakhary RG, Seremetis S. Recombinant activated Factor VII in major surgery and trauma patients: a response [comment]. <i>Expert Opinion on Drug Safety</i> 2005;4(5):813-814.	Ineligible study design
Zangrillo A, Mizzi A, Biondi-Zoccai G, et al. Recombinant activated factor VII in cardiac surgery: a meta-analysis. <i>Journal of Cardiothoracic & Vascular Anesthesia</i> 2009;23(1):34-40.	Ineligible study design
Zibaitis A, Schumann R. Abdominal compartment syndrome following complete abruption of the placenta, fetal demise and consumptive coagulopathy. <i>Anesthesiology (Hagerstown)</i> 2004;100(5):B67.	Ineligible study design

Excluded article	Reason for exclusion
Zietkiewicz M, Garlicki M, Domagala J, et al. Successful use of activated recombinant factor VII to control bleeding abnormalities in a patient with a left ventricular assist device. <i>J Thorac Cardiovasc Surg</i> 2002;123(2):384-385.	Small sample size
Zimmerman RD, Maldjian JA, Brun NC, et al. Radiologic estimation of hematoma volume in intracerebral hemorrhage trial by CT scan. <i>ANNR: American Journal of Neuroradiology</i> 2006;27(3):666-670.	Duplicate
Zimring JC. Appropriate use of recombinant factor VIIa: an expanding and unanswered question. <i>Transfusion</i> 2004;44(11):1544-1546.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Zirphile X, Debien B, Perez JP, et al. Is Novoseven (R) useful in war traumatology? <i>Medecine et Armees</i> 2008;36(1):3-9.	Ineligible study design
Zulfikar B, Kayiran SM. Successful treatment of massive gastrointestinal hemorrhage in acute biphenotypic leukemia with recombinant factor VIIa (NovoSeven). <i>Blood Coagulation & Fibrinolysis</i> 2004;15(3):261-263.	Ineligible study design
Zupancic Salek S, Sokolic V, Viskovic T, et al. Successful use of recombinant factor VIIa for massive bleeding after caesarean section due to HELLP syndrome. <i>Acta Haematol</i> 2002;108(3):162-163.	Ineligible study design
Zupancic-Salek S, Kovacevic-Metelko J, Radman I. Successful reversal of anticoagulant effect of superwarfarin poisoning with recombinant activated factor VII. <i>Blood Coagulation & Fibrinolysis</i> 2005;16(4):239-244.	Ineligible study design
Zuppa AF, Nadkarni VM. Recent developments in the pharmacologic approach to pediatric critical care. <i>Current Opinion in Anaesthesiology</i> 2004;17(3):223-228.	Ineligible study design

Appendix C. Additional Analyses, Tables, and Figures

Appendix Table 1. Diagnostic hierarchy and ICD-9-CM diagnosis and procedure codes

Rank in Hierarchy	Description	ICD-9-CM Codes (PR for procedure codes) Coding based on the presence of any eligible code within a hospitalization
1	Hemophilia A and B	286.0, 286.1
2	Hemophilia-related off-label	286.2, 286.3, 286.4, 286.5, 287.1, 287.3, 287.9
3	Brain trauma	852, 853
4	Body trauma	All E-codes except E85, E87, E92, E93, E94; PR 81-90, 92-95, 98
5	Intracranial hemorrhage	430, 431, 432
6	Brain surgery	PR 1
7	Pediatric cardiac surgery	PR 35, 36, 37 (except 37.2) and age <18
8	Adult cardiac surgery	PR 35, 36, 37 (except 37.2) and age ≥18
9	Obstetrics	72, 73, 74, 75; PR 63, 64, 65, 66, 67 (except 67.8)
10	Neonatal conditions	V3, 76, 77 (except for 76.0, 76.1, 76.2, 76.3) and age < 1 year
11	Aortic aneurysm	441
12	Prostatectomy	PR 60
13	Other vascular surgery	PR 39 (except 39.94, 39.95, 39.96)
14	Liver transplantation	PR 50.5
15	Liver biopsy	PR 50.1, 50.2
16	Esophageal varices	456.0, 456.1, 456.2
17	Other liver disease	571, 572
18	Other gastrointestinal bleed	530.4, 531-535, 537, 557, 562, 569, 578
19	Other secondary hematological conditions	287 (except 287.1, 287.3, 287.9), 446.6, 283.1, 286.6, 286.7, 286.9, 964.2, V58.61, V58.63, E585.2, E934.2
20	Pulmonary disease	786.3, 770.3; PR 32, 33, 34
21	Cancer	140-230
22	Other surgical procedures	PR ≤ 87 (except 39.8)
23	Other, without procedures	All remaining codes

Appendix Table 2. Characteristics of included studies: Sample sizes, patient age, rFVIIa dose, and outcomes

Study Design	Number of Studies	Total Number of rFVIIa Patients	rFVIIa Sample Size Range	rFVIIa Mean Age Range	rFVIIa Mean Dose Range, ug/kg	Important Outcomes Evaluated	
						Direct	Indirect
KQ2-4 Indications							
Intracranial hemorrhage							
RCT	4	944	36 - 573	51 - 72	5 - 160	Mortality, TE events, Functional outcome	Change in hematoma volume
Comparative observational	4	88	5 - 46	60 - 77	10 - 100	Mortality, TE events, Functional outcome	Change in hematoma volume
Non-comparative	3	53	15 - 20	8 - 68	60 - 100	Mortality, TE events, Functional outcome	Change in hematoma volume
Body trauma							
RCT (1 article reports on 2 RCTs)	2	139	139	29 - 33	400	Mortality, TE events, ARDS	Transfusion requirements, Hospital/ICU length of stay
Comparative observational	5	264	29 - 81	28 - 41	50 - 120	Mortality, TE events, ARDS	Transfusion requirements, Hospital/ICU length of stay
Non-comparative	4	204	15 - 108	7 - 38	74 - 140	Mortality, TE events	Transfusion requirements
Brain trauma							
RCT	1	61	61	52	40 - 200	Mortality, TE events	Change in hematoma volume
Comparative observational	2	60	29 - 31	40	NR	Mortality, TE events	Time to neurosurgery, Hospital/ICU length of stay
Non-comparative	1	15	15	61	59	-	-
Liver transplantation							
RCT	4	209	10 - 121	49 - 53	20 - 360	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay, Operating time
Comparative observational	4	51	6 - 28	13 - 48	20 - 80	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay, Operating time
Non-comparative	0	-	-	-	-	-	-
Adult cardiac surgery							
RCT	2	114	10 - 104	63 - 70	40 - 90	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay
Comparative observational	6	191	17 - 51	56 - 70	19 - 100	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay, Need for surgical re-exploration
Non-comparative	11	1125	16 - 503	51 - 68	10 - 103	Mortality, TE events	Transfusion requirements, Blood loss, Need for surgical re-exploration

Study Design	Number of Studies	Total Number of rFVIIa Patients	rFVIIa Sample Size Range	rFVIIa Mean Age Range	rFVIIa Mean Dose Range, ug/kg	Important Outcomes Evaluated	
						Direct	Indirect
Pediatric cardiac surgery							
RCT	1	40	40	0.33	63	TE events	Transfusion requirements, Blood loss, Time to chest closure
Comparative observational	3	48	9 - 24	0.03 - 9	43 - 282	TE events	Transfusion requirements, Blood loss, Need for surgical re-exploration
Non-comparative	0	-	-	-	-	-	-
Prostatectomy							
RCT	1	24	24	61 - 64	20 - 40	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay, Operating time
Comparative observational	0	-	-	-	-	-	-
Non-comparative	0	-	-	-	-	-	-
KQ1 Indications:							
Other liver disease							
RCT	4*	517	71 - 170	46 - 55	5 - 800	Mortality, TE events	Transfusion requirements, Blood loss, Efficacy of bleeding control
Comparative observational	1	7	7	34	40 - 80	Mortality	Transfusion requirements, Efficacy of bleeding control, Ability to place ICP transducer
Obstetrics/gynecology							
RCT	0	-	-	-	-	-	-
Comparative observational	3	50	6 - 26	29 - 34	70 - 100	Mortality, TE events	Transfusion requirements, Blood loss
Hematology/oncology							
RCT	2	93	16 - 77	9 - 23	100 - 1120	Mortality, TE events	Transfusion requirements, Efficacy of bleeding control
Comparative observational	1	24	24	NR	NR	Mortality, TE events	Requirement for positive pressure ventilation, Hospital/ICU length of stay
Other surgery							
RCT	4	191	9 - 122	44 - 56	20 - 360	Mortality, TE events	Transfusion requirements, Blood loss, Operating time, Hospital/ICU length of stay
Comparative observational	2	55	26 -29	17 - 60	23	Mortality, TE events, Functional outcome	Transfusion requirements, Blood loss

Study Design	Number of Studies	Total Number of rFVIIa Patients	rFVIIa Sample Size Range	rFVIIa Mean Age Range	rFVIIa Mean Dose Range, ug/kg	Important Outcomes Evaluated	
						Direct	Indirect
Total							
RCT	24	2310	9 - 573	0.33 - 72	5 - 1120		
Comparative observational	31	756	5 - 81	0.03 - 71	17 - 120		
Non-comparative	19	1166	15 - 503	20 - 68	59 - 140		

RCT=randomized controlled trial; TE=thromboembolic; ICU=intensive care unit

Appendix Table 3. Mortality and thromboembolic events in studies included in harms analyses

Article	Study Design	Sample Size	Mean Age (SD) [Range]	Mean Dose (ug/kg) (SD) [Range]	Mortality	TE Rate
Intracranial hemorrhage						
Mayer 2005a ²³ (3 arms)	RCT	108	67 (12)	40	0.18	0.06
		92	65 (12)	80	0.18	0.04
		103	64 (13)	160	0.19	0.10
Mayer 2005b ⁸⁶ (6 arms)	RCT	6	51 (9)	10	0	0
		6	68 (22)	20	0	0.33
		6	68 (16)	40	0.17	0.33
		6	58 (11)	80	0	0
		6	64 (14)	120	0.17	0
		6	53 (12)	160	0.17	0
Mayer 2006 ⁸⁷ (4 arms)	RCT	8	72 (10)	5	0.25	0
		8	60 (15)	20	0.25	0.25
		8	64 (13)	40	0.38	0.13
		8	62 (12)	80	0	0
Mayer 2008 ⁸⁸ (2 arms)	RCT	276	65 (14)	20	0.18	0.09
		297	65 (13)	80	0.21	0.12
Pickard 2000 ⁹⁰	Comparative Observational	5	NR	80	NR	0.20
Brody 2005 ⁹¹	Comparative Observational	12	71 (13.1)	NR	0.42	0.17
Hallevi 2008 ⁹²	Comparative Observational	46	59.6 [38-87]	80 ^U [40;80]	0.13	0.15
Ilyas 2008 ⁸⁹	Comparative Observational	15	76.5 (11)	24 [10-100]	0.21	0.04
Sutherland 2008 ⁹³	Non-Comparative Observational	15	68.0 ^U [25 -81]	60 ^U [40-92]	0.13	0
Nussbaum 2009 ⁹⁵	Non-Comparative Observational	18	56.8	100	0.22	0.44
Herbertson 2008 ⁹⁴	Non-Comparative Observational (Pediatric)	20	7.7	100	0.15	0
Body trauma						
Boffard 2005 ⁹⁶ (blunt arm)	RCT	69	33 (13)	400	0.25	0.03
Boffard 2005 ⁹⁶ (penetrating arm)	RCT	70	29 (10)	400	0.24	0.06
Rizoli 2006 ^{97a}	Comparative Observational	38	36.8 [30.6-43.1]	NR	0.50	NR
Nascimento 2008 ^{181a}	Comparative Observational	72	NR	NR	NR	0.10
Harrison 2005 ¹⁰¹	Comparative Observational	29	40.9 (20.8)	60 [40-80]	0.41	0.07
Fox 2009 ⁹⁹	Comparative Observational	53	27.5 (9.5)	100 [90-120]	0.07	0.12
Dutton 2004 ^{100b}	Comparative Observational	81	40.8 (21)	97.8	0.58	NR
Cameron 2007 ¹⁰²	Non-Comparative Observational	108	38.0 ^U [11-91]	90 ^U [78-105] ^l	0.42	0.03
Felfernig 2007 ¹⁰³	Non-Comparative Observational	45	30.5 [5-81]	73.6 (27)	0.24	NR
Thomas 2007 ^{228b}	Non-Comparative Observational	242	44.0 (21)	68 ^{&} (45)	NR	0.11
Martinowitz 2005 ¹⁰⁴	Non-Comparative	36	19.5	140 ^U	0.39	NR

Article	Study Design	Sample Size	Mean Age (SD) [Range]	Mean Dose (ug/kg) (SD) [Range]	Mortality	TE Rate
	Observational		[14-65]	[70-540]		
Perkins 2007 ^{182c}	Non-Comparative Observational	53	23.1	109 ^{&}	0.34	0.02
Alten 2009 ¹⁰⁵	Non-Comparative Observational (Pediatric)	15	7	88	0.13	0.07
Herbertson 2008 ⁹⁴	Non-Comparative Observational (Pediatric)	37	7.7	100	0.22	0
Brain trauma						
Narayan 2008 ¹⁰⁶ (5 arms)	RCT	12	51.5 (21.5) [^]	40	0	0.17
		11		80	0	0.18
		14		120	0.07	0.21
		12		160	0.17	0
		12		200	0.33	0.17
Stein 2008 ^{107b}	Comparative Observational	29		[8-140]	0.35	0.21
Bartal 2007 ¹⁰⁹	Non-Comparative Observational	15	61.0 (11)	59 ^{&} [40-90]	0.07	0
Liver Transplantation						
Pugliese 2007 ¹¹²	RCT	10	NR	40	NR	0
Lodge 2005 ¹¹⁰ (2 arms)	RCT	63	53.3 (11.2)	180	0.02 [#]	0.19
		58	52.6 (9.2)	360	0.03 [#]	0.12
Planinsic 2006 ¹¹¹ (3 arms)	RCT	18	49.4 (13.4)	20	0.06 [#]	0.11 [*]
		24	49.7 (10.1)	40	0.08 [#]	0.04 [*]
		22	51.9 (8.8)	80	0.05 [#]	0.09 [*]
Liu 2009 ¹¹³	RCT	14	51.9 [36-54]	47.5 [41-65]	NR	0
Hendriks 2001 ¹¹⁴	Comparative Observational	6	43 ^U [37-61]	80	0	0.17
Kalicsinski 2005 ¹¹⁶	Comparative Observational	28	13.2 (4.2)	51.5 [30-100]	0.07	0
Niemann 2006 ¹¹⁷	Comparative Observational	11	48 (15)	58 (18)	0	0
De Gasperi 2005 ¹¹⁵	Comparative Observational	6	45 (4)	30 ^{&} [20-40]	0	NR
Adult Cardiac Surgery						
Diprose 2005 ¹¹⁸	RCT	9	63 ^U [59-66] ^l	90	0	0.22
Gill 2009 ¹¹⁹ (2 arms)	RCT	35	63.6 [^]	40	0.11	0.09
		68	63.6 [^]	80	0.09	0.06
Gelsomino 2008 ¹²¹	Comparative Observational	40	70.1 (9.2)	18 ^U [9-16] ^l	0.05	0.05
von Heymann 2005 ¹²³	Comparative Observational	26	63.5 (12.87)	89.3 ^{&}	0.38	0
Bowman 2008 ¹²⁴	Comparative Observational	36	58	100 ^{&}	0.08	0.11
Trowbridge 2009 ¹²⁵	Comparative Observational	17	70 (9)	NR	NR	NR
Tritapepe 2007 ¹²²	Non-Comparative Observational	23	62.4 (9.4)	82 ^{&}	0.13	0.09
Karkouti 2006 ^{215d}	Non-Comparative Observational	114	59.0 (17)	56 (25)	0.16	0.20

Article	Study Design	Sample Size	Mean Age (SD) [Range]	Mean Dose (ug/kg) (SD) [Range]	Mortality	TE Rate
Dunkley 2008 ¹³³	Non-Comparative Observational	293	63.0 (15)	92.3 ^U [82-103] ^I	0.17	0.14
Filsoufi 2006 ¹²⁶	Non-Comparative Observational	17	65.0 (18)	103.1 (30.2)	0.29	NR
Gandhi 2007 ¹²⁷	Non-Comparative Observational	17	53.0 [38-64]	78.3 [24-189]	0.29	0.24
Hyllner 2005 ¹²⁸	Non-Comparative Observational	24	60.0 [34-82]	72.2 [*] [19.2-104]	0.29	NR
McCall 2006 ¹²⁹	Non-Comparative Observational	53	68.0 [55- 75] ^I	90 (15)	0.19	NR
Raivio 2005 ¹³⁰	Non-Comparative Observational	16	60 (14.9)	65 [24-192]	0.25	0.25
Aggarwal 2004 ¹³¹	Non-Comparative Observational	24	65.0 ^U [26-85]	90	0.75	NR
Karkouti 2008 ¹³²	Non-Comparative Observational	503	62.0 (15)	62 ^U [40-89] ^I	0.32	0.24
Bruckner 2009 ¹³⁴ (2 doses)	Non-Comparative Observational	32	51	15	0	0.09
		30	51	20	0.87	0.37
Masud 2009 ¹³⁵	Non-Comparative Observational	93	60.6	56.2	0.23	0
Hsia 2009 ¹³⁶	Non-Comparative Observational	23	NR	NR	NR	0.39
Pediatric Cardiac Surgery						
Ekert 2006 ¹³⁷	RCT	40	0.33	63 [40-80]	NR	0
Agarwal 2007 ¹³⁸	Comparative Observational	24	0.0 ^U [0.01-6.53]	59.8 ^{&}	NR	0.08
Tobias ¹³⁹	Comparative Observational	9	9 (4)	90	NR	0
Niles 2008 ¹⁴⁰ (2 groups)	Comparative Observational	11	60 days (99)	166 [76-282]	0	0
		4	14.5	286 [26-956]	0	0
Prostatectomy						
Friederich 2003 ¹⁴¹ (2 arms)	RCT	8	61 (8.9)	20	0	0.13
		16	64 (8.5)	40	0	0

Fair+ Comparative Observational, fair or good quality comparative observational studies also included in the effectiveness review in Key Questions 2-4; Variance (e.g. standard deviation, range, or IQR) left blank if not reported.

^UMedian

^IInterquartile Range

[^]Mean age (and standard deviation) for all study arms combined.

[#]Mortality is underestimated because 2 deaths each in Lodge et al.¹¹⁰ and Planinsic et al.¹¹¹ were not reported by treatment arm.

^{*}Thromboembolic events are underestimated because only arterial thromboembolic events were counted in Planinsic et al.¹¹¹

[&]Mean dose estimated from mean or median size of individual doses, or converted from mg to ug/kg by assuming an average patient weight.

^aNascimento et al.¹⁸¹ was used instead Rizoli et al.⁹⁷ for the analysis of thromboembolic events. Nascimento et al. is a continuation of Rizoli et al. with more patients.

^bDutton et al.¹⁰⁰ and Thomas et al.²²⁸ have overlapping patient populations. Dutton et al. was used for the mortality analysis and Thomas et al. was used in the analysis of thromboembolic events for body trauma. Thomas et al. included traumatic brain injury patients, some of which were included in Stein et al.¹⁰⁷ Thus, some patients are double counted between the brain trauma and the body trauma analyses of thromboembolic events.

^cData on mortality and thromboembolic events from Perkins et al.¹⁸² (an overlapping non-comparative study) are used instead of Spinella et al.⁹⁸ (a comparative observational study analysed in the body trauma section above) because the former has a larger sample size.

^dData from the 2006 study by Karkouti et al.²¹⁵ was used instead of the 2005 study by Karkouti et al.¹²⁰ The 2006 study is an overlapping non-comparative study with more patients.

Appendix Table 4. Clinical trials on the off-label use of rFVIIa that are registered on an online database

Trial ID	Topic	Sponsor	End date	Primary associated publications
Key Question 2-4 Indications				
Novo Nordisk trial # F7ICH-1389	Intracranial hemorrhage	Novo Nordisk	Oct 2002	Article: 2005 ⁸⁶
Novo Nordisk trial # F7ICH-2073	Intracranial hemorrhage	Novo Nordisk	Mar 2003	Article: 2006 ⁸⁷
NCT00426803	Intracranial hemorrhage	Novo Nordisk	Jun 2004	Article: 2005, ²³
NCT00222625	Intracranial hemorrhage	University of Perugia	Sep 2006	Article: 2008 ²³⁸
NCT00127283	Intracranial hemorrhage	Novo Nordisk	Feb 2007	Article: 2008 ²³⁹
NCT0026606	Intracranial hemorrhage	Novo Nordisk	Apr 2007	None*
NCT00128050	Intracranial hemorrhage	IRCCS Policlinico S. Matteo	Dec 2008	None
NCT00770718	Intracranial hemorrhage	University of Utah	Apr 2010	NA
NCT00810888	Intracranial hemorrhage	University of Cincinnati	Apr 2013	NA
Novo Nordisk trial # F7TRAUMA-2159	Body trauma (2 RCTs merged) [^]	Novo Nordisk	Sep 2003	Article: 2005 ⁹⁶
NCT00184548 merged with NCT00323570	Body trauma (2 RCTs merged) [^]	Novo Nordisk	Sep 2008 (terminated) [†]	None*
NCT 00123591	Brain trauma	Novo Nordisk	May 2006	Article: 2008 ¹⁰⁶
Novo Nordisk trial # F7LIVER-1256	Liver transplantation	Novo Nordisk	Sep 2003	Article: 2005 ¹¹⁰
NCT00154427	Adult cardiac surgery	Novo Nordisk	Nov 2007 (terminated) [‡]	Article: 2009 ¹¹⁹
NCT00214656	Adult cardiac surgery	Austin Health	Jun 2008	None
Novo Nordisk trial # F7CPB-3343	Pediatric cardiac surgery	Novo Nordisk	NS	Article: 2006 ¹³⁷
Other Indications				
Novo Nordisk trial # F7-3015	Children with dengue hemorrhagic fever	Novo Nordisk	Dec 2002	Article: 2005 ¹⁵⁰
Novo Nordisk trial # F7LIVER-1313	Partial hepatectomy in patients with cirrhosis	Novo Nordisk	Dec 2002	Article: 2006 ¹⁴⁴
Novo Nordisk trial # F7BMT-1360	Allogenic stem cell transplantation	Novo Nordisk	Oct 2003	Article: 2005 ¹⁵¹
Novo Nordisk trial # F7SCT-1485	Allogenic stem cell transplantation	Novo Nordisk	Oct 2003 (terminated) [§]	None*
Novo Nordisk trial # F7HAEM-2080	Hemorrhagic cystitis	Novo Nordisk	Nov 2003	Article: 2006 ²⁴⁰
NCT00104455	Bleeding in healthy volunteers	Novo Nordisk	Nov 2004	Abstracts 2005 ²⁴¹⁻²⁴³

Trial ID	Topic	Sponsor	End date	Primary associated publications
Novo Nordisk trial # F7ORTHO-1506	Acetabular reconstruction surgery	Novo Nordisk	Mar 2005	Article: 2005 ¹⁵⁴
NCT0010237	Spinal surgery	Novo Nordisk	Feb 2006	Article: 2007 ¹⁵⁶
NCT00154492	Variceal bleeding	Novo Nordisk	Aug 2006	Abstract 2007 ²⁴⁴
Novo Nordisk trial # F7HAEM-1825	Bleeding in healthy volunteers treated with warfarin	Novo Nordisk	Jul 2008	None*
NCT00370877	Postpartum hemorrhage	Centre Hospital University of Nimes	Dec 2009	NA
NCT00192933	Hemorrhage††	Rigshospitalet, Denmark	Dec 2010	NA
NCT00243243	Burns	United States Army Institute of Surgical Research	Dec 2010	NA

NA=not applicable. NS=not stated (checked via applicable websites and subsequent publications)

*Synopsis of results available at Novo Nordisk website: www.novonordisk.com (last accessed 10/19/09)

^According to manufacturer web site, each of these trials included 2 related RCTs: one directed at patients with blunt trauma and the other at patients with penetrating trauma.

†According to the manufacturer web site, “The decision to discontinue the F7TRAUMA-1711 trial is not due to any safety concerns. The result of the pre-planned futility analysis performed in June 2008 predicted a very low likelihood of reaching a successful outcome on the primary efficacy endpoint at the end of the trial and as a consequence, the company has decided to close the trial at this juncture.”

‡According to manufacturer web site, “The trial was terminated after recruiting 172 patients but without proceeding to the highest dosing cohort as this no longer reflects common clinical practice.”

§According to the manufacturer web site, “Trial enrollment of this study was prematurely terminated due to excessively slow patient recruitment.”

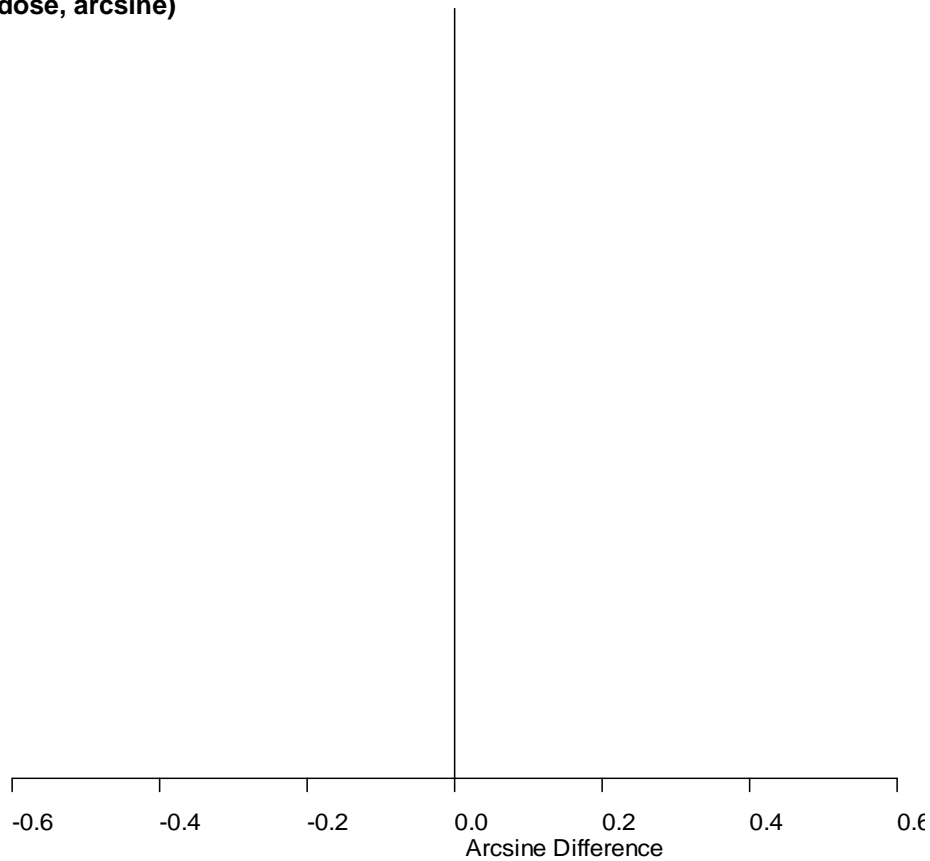
††May be a prospective cohort study, rather than a clinical trial.

Appendix Table 5. Non-English language articles on key questions 2-4 indications excluded on the basis of language

Article citation	Language	Information available for review in English	Clinical indication	Patient information
RCT				
Ma B, Wang ZN, Zhang BR. Effect of recombinant activated factor VII a on early recovery of patients undergoing cardiac valve replacement under cardiopulmonary bypass: a randomized double-blind placebo-controlled trial. <i>Dier Junyi Daxue Xuebao</i> . 2006;27(10):1110-3.	Chinese	Abstract and tables within full publication	Adult cardiac surgery	11 rFVIIa, 11 placebo
Comparative observational study				
Novak V, Mitov L, Rancić Z, Petrović B, Novak M. The use of recombinant activated factor VII in traumatic intracranial haemorrhage. <i>Srpski Arhiv Za Celokupno Lekarstvo</i> 2008;136 Suppl 3: 193-8.	Serbian	Abstract and tables within full publication	Brain trauma	7 rFVIIa, number of controls unclear
Case report, case series, or registry				
Grintescu I, Tulbure D, Mirea L. [Activated recombinant factor VII (Novoseven) in multiple trauma patients: an outcome analysis]. <i>Chirurgia (Bucuresti)</i> . 2006;101(6):615-24.	Romanian	Abstract	Body trauma	34 patients
Demytyeva II, Sandrikov VA, Charnaya MA, Morozov YA, Trekova NA, Eremenko AA. The "NovoSeven" (rFVIIa) hemostatic in massive hemorrhages in patients operated on the heart and aorta. <i>Anesteziologiya i Reanimatologiya</i> . 2004(5):11-13.	Russian	Abstract	Adult cardiac surgery	25 patients
Demytyeva II, Gladysheva VG, Charnaya MA, Morozov YA. Influence of recombinant activated factor VIIa thrombocytic hemostasis. <i>Gematologiya i Transfuziologiya</i> . 2005;50(6):12-15.	Russian	Abstract	Adult cardiac surgery	15 patients
Dement'eva I, Gladysheva VG, Charnaia MA, Morozov lu A. [On the mechanism of action of recombinant activated factor VII in massive non-hemophylic bleeding in cardiosurgical patients]. <i>Vestn Ross Akad Med Nauk</i> . 2006(12):21-5.	Russian	Abstract	Adult cardiac surgery	35 patients
Gong ZY, Gao CQ, Xiao CS, et al. [The use of recombinant activated factor VII for blood loss after cardiovascular surgery]. <i>Chung-Hua Wai Ko Tsa Chih [Chinese Journal of Surgery]</i> . 2008;46(19):1497-501.	Chinese	Abstract	Adult cardiac surgery	16 patients
Lacheva A, Georgiev S, Pilosoff V, Lazarov S, Mitev P. Administration of recombinant factor VIIA for the management of massive postoperative blood loss in children with congenital heart defects. <i>Anaesthesiology and Intensive Care</i> . 2008;35(2):3-8.	Bulgarian	Abstract	Pediatric cardiac surgery	30 patients

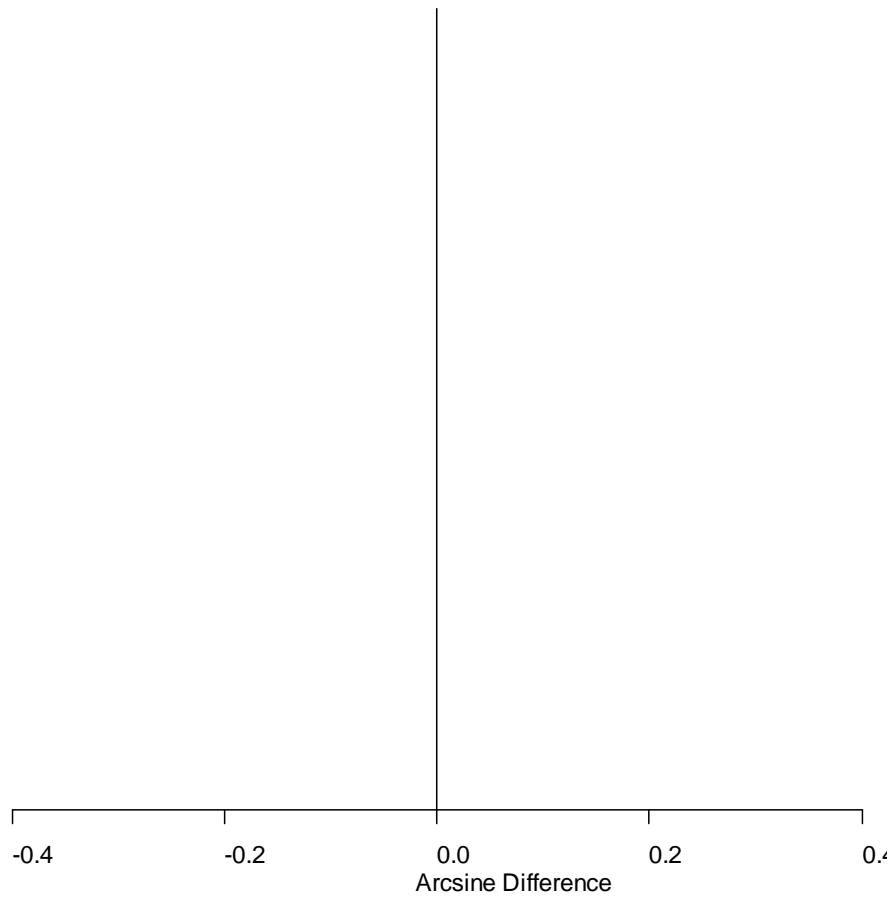
Appendix Figure 1. Mortality in ICH (low rFVIIa dose, arcsine)

Appendix Figure 2. Mortality in ICH (medium rFVIIa dose, arcsine)



Article	Deaths/total patients (low dose)		Deaths/total patients (medium dose)	
	rFVIIa	Control	rFVIIa	Control
Mayer 2005a	19/108	28/96	17/92	28/96
Mayer 2005b	1/18	2/11	0/6	2/11
Mayer 2006	7/24	1/8	0/8	1/8
Mayer 2008	50/276	51/268	62/297	51/268

Appendix Figure 3. Mortality in ICH (high rFVIIa dose, arcsine)

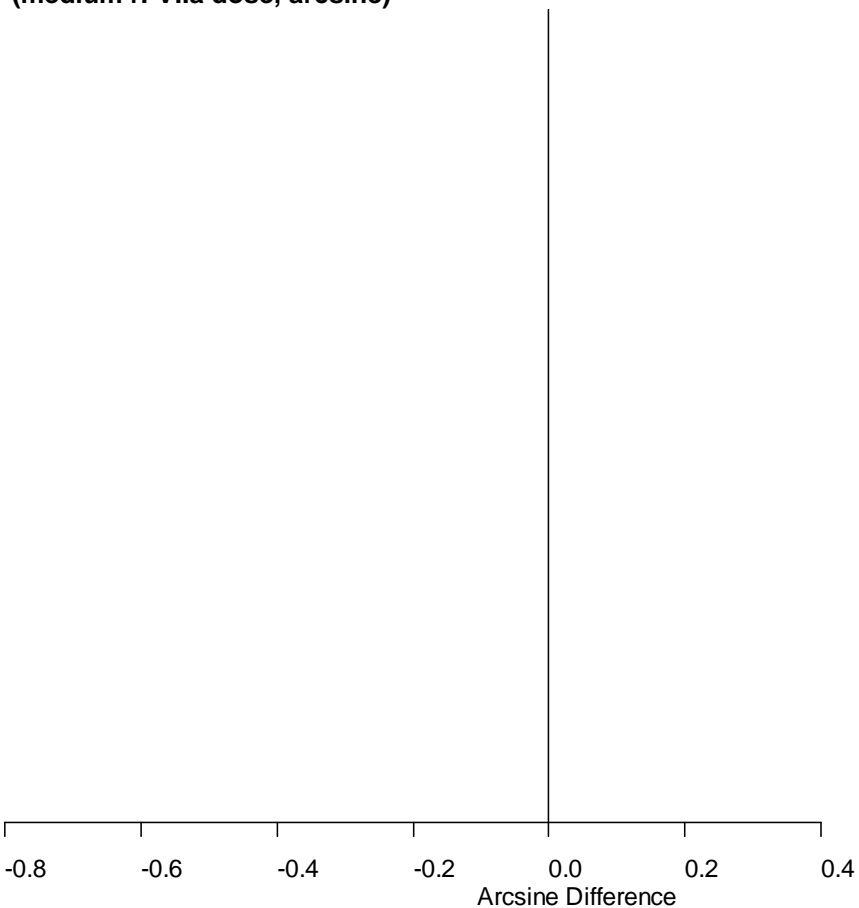


Article	Deaths/Total patients (high dose)	
	rFVIIa	Control
Mayer 2005a	20/103	28/96
Mayer 2005b	2/12	2/11

Appendix Figure 4. Poor modified Rankin score in ICH (low rFVIIa dose, arcsine)

Article	Poor mRS/Total patients (low dose)	
	rFVIIa	Control
Mayer 2005a	59/108	66/96
Mayer 2005b	6/18	5/11
Mayer 2006	13/24	4/8
Mayer 2008	130/264	122/262

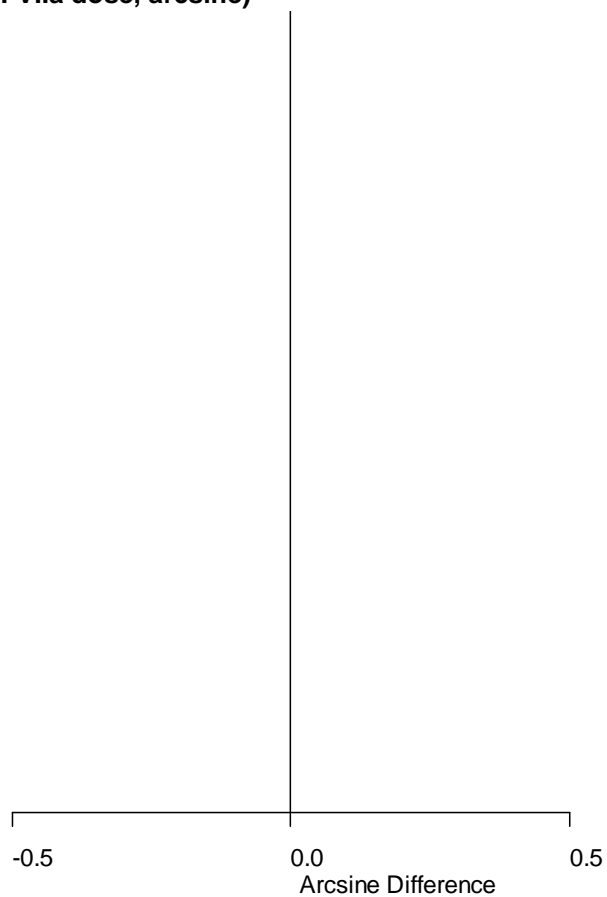
Appendix Figure 5. Poor modified Rankin score in ICH patients (medium rFVIIa dose, arcsine)



Appendix Figure 6. Poor modified Rankin score in ICH (high rFVIIa dose, arcsine)

Article	Poor mRS/total patients (medium dose)		Poor mRS/total patients (high dose)	
	rFVIIa	Control	rFVIIa	Control
2005a	45/91	66/96	56/103	66/96
2005b	3/6	5/11	7/12	5/11
2006	2/8	4/8	NA	NA
2008	148/293	122/262	NA	NA

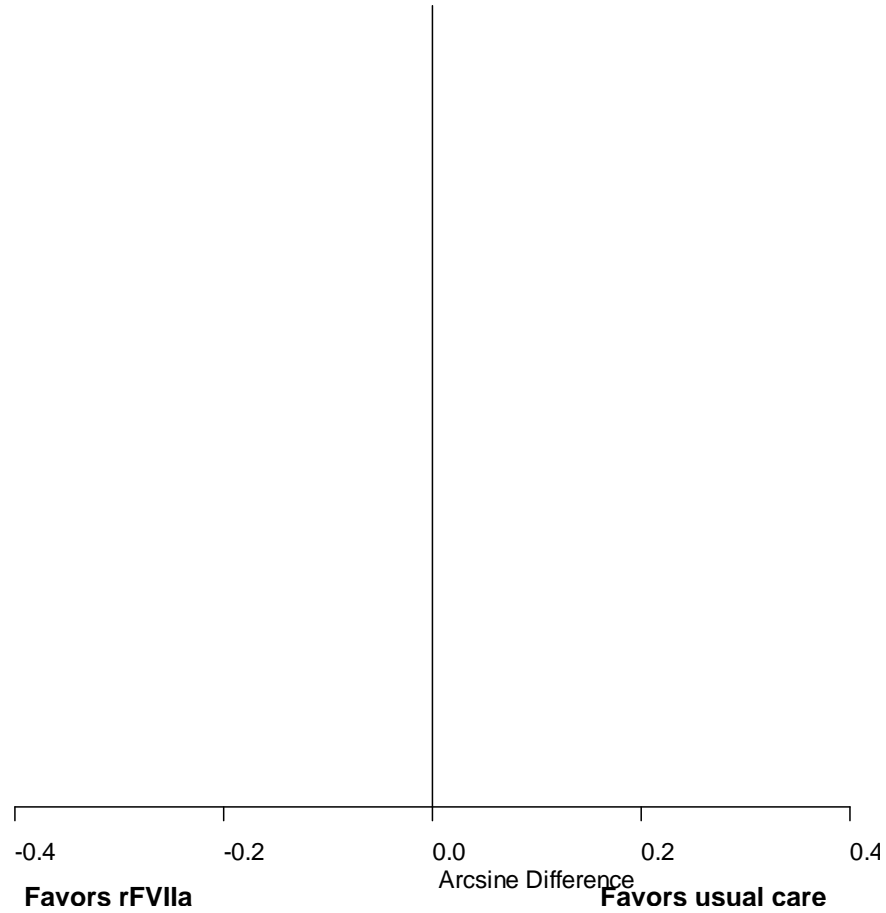
Appendix Figure 7. Arterial thromboembolic events in ICH (low rFVIIa dose, arcsine)



Appendix Figure 8. Arterial thromboembolic events in ICH (medium rFVIIa dose, arcsine)

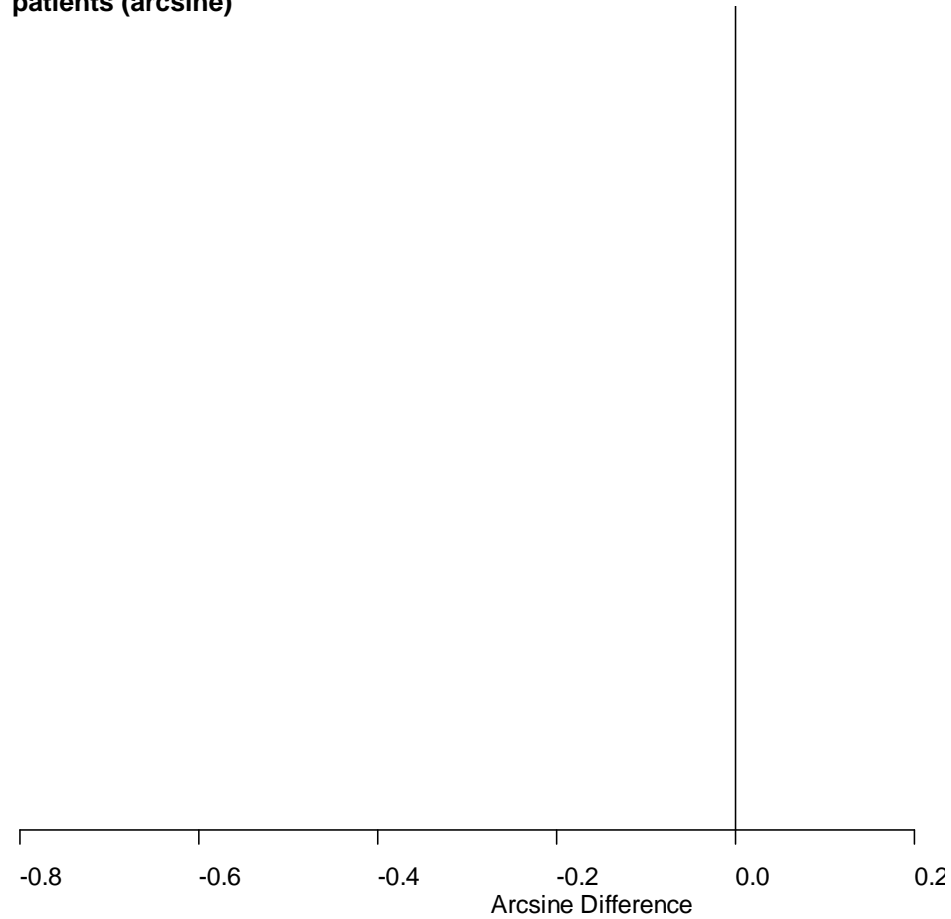
Article	Arterial TE events/total patients (low dose)		Arterial TE events/total patients (medium dose)	
	rFVIIa	Control	rFVIIa	Control
Mayer 2005a	6/108	0/96	2/92	0/96
Mayer 2005b	3/18	0/11	0/6	0/11
Mayer 2006	0/24	1/8	0/8	1/8
Mayer 2008	15/265	12/263	27/293	12/263

Appendix Figure 9. Arterial thromboembolic events in ICH (high rFVIIa dose, arcsine)



Article	Arterial TE events/Total patients (high dose)	
	rFVIIa	Control
Mayer 2005a	8/103	0/96
Mayer 2005b	0/12	0/11

Appendix Figure 10. Mortality in adult cardiac patients (arcsine)

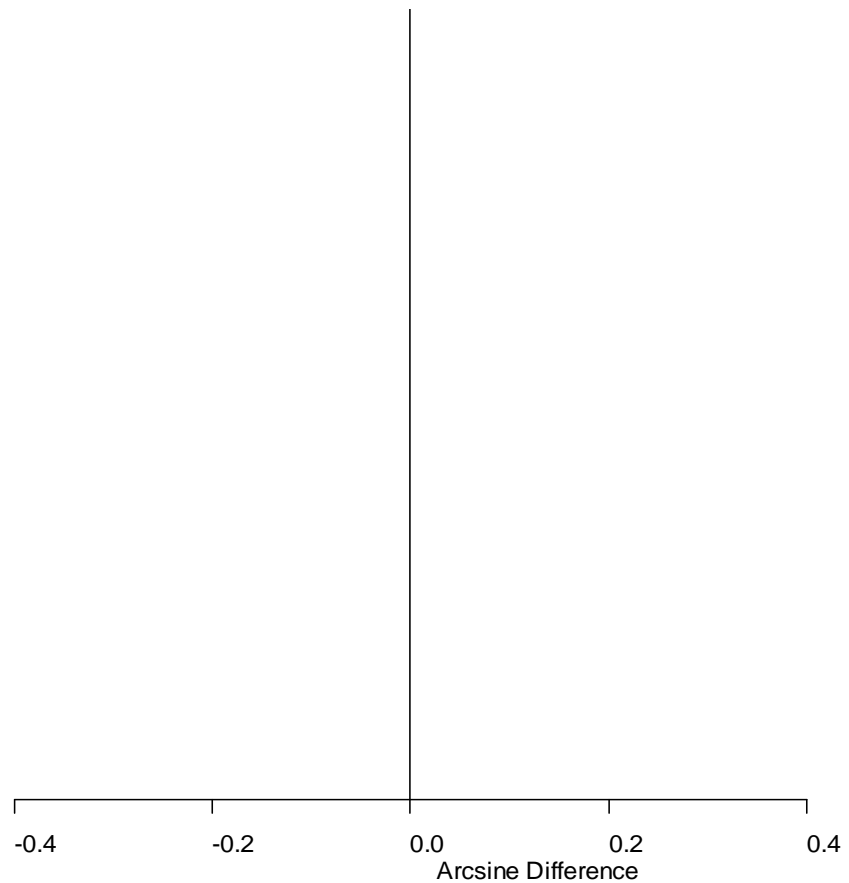


Appendix Figure 11. Sensitivity analysis for mortality in adult cardiac patients incorporating Chinese RCT (arcsine)

Article	Deaths/Total Patients	
	rFVIIa	Control
Diprose 2005	0/9	1/10
Karkouti 2005	7/51	7/51
Gelsomino 2006	2/40	3/40
Gill 2009	10/103	4/69
Ma 2006	0/11	0/11

Appendix Figure 12. All thromboembolic events in adult cardiac patients (arcsine)

Appendix Figure 13. Sensitivity analysis for all thromboembolic events in adult cardiac patients incorporating Chinese RCT (arcsine)



Appendix D. Peer Reviewers

Jay Lozier, M.D., Ph.D., National Institutes of Health Clinical Center, Bethesda, MD

Dr Simon Stanworth/ Prof Chris Hyde, NHSBT, John Radcliffe Hospital, Headington, Oxford

Richard P. Dutton, M.D., M.B.A., University of Maryland, Department of Anesthesiology, Baltimore, MD

M. Margaret Knudson, Department of Surgery, Ward 3A, San Francisco General Hospital, San Francisco, CA

Rochelle Fu, Methodologist/statistician from SRC

Maureane Hoffman, M.D., Ph.D., Durham VA Medical Center, Durham, NC

Stefan Mayer

Bertil Glader, M.D., Ph.D., Lucile Packard Children's Hospital, Stanford, CA.

Per Falk, MD, PhD, Associate Professor, Vice President, Clinical Development, Medical & Regulatory Affairs, Novo Nordisk, Inc.

Appendix E. Study Abstraction Forms

Level 1. (Screening Title and Abstract) Abstraction Form

1. Does this article discuss the use of recombinant factor VIIa in vivo in humans who do not have hemophilia?
(choose one)

No, is NOT on recombinant factor VIIa

No, is on recombinant factor VIIa but is ...: ***(do not check this circle, choose from an option below)***

...in patients who have hemophilia (congenital or acquired)

...in other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)

...is used in humans in vivo, but is NOT used as a therapy or for clinically relevant outcomes

...in animals or in vitro (in culture, molecular, or laboratory studies only)

Yes

Can't tell

Exclude for other reason(s), specify

2. Is in a foreign language

Yes

No

3. For an article that will NOT proceed to full review, is the article still possibly of interest to the research?

Yes

No

Level 2. (Full Text Article Screening) Abstraction Form

1. Is the focus/study population any of the following?

Is NOT on rFVIIa

Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)

Other populations with congenital or chronic acquired bleeding or clotting disorders (e.g., Glanzmann's)

In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes

Animals or in vitro (in culture, molecular, or laboratory studies)

2. What is/are the indication(s) for giving rFVIIa? (Check all that apply.)

Intracranial bleeding

Bleeding secondary to trauma

Liver transplant, operative bleeding (whether to prevent or treat)

Cardiac surgery, operative bleeding (whether to prevent or treat)

Prostatectomy, operative bleeding (whether to prevent or treat)

Other indication(s), specify:

Can't tell

3. Is this a secondary report of an already published article (e.g., is on the same study, but with longer follow-up or on a different outcome variable)?

Yes, and specify ref ID# here, if found:

4. What type of article is this?

RCT/ Quasi-RCT (If quasi-RCT, specify why)

Observational study: includes cohort, cross-sectional, case-control and other study types (but NOT case series or report)

Case series or case report

All other (For an article that addresses a KQ1 INDICATION ONLY and is a type of article not mentioned above, check this box only and then skip to question 5. For an article that addresses a KQ2-4 INDICATION ONLY and is a type of article not mentioned above, do NOT check this box; instead check the relevant box immediately below. For an articles that addresses BOTH KQ1 AND KQ2-4 INDICATIONS and is a type of article not mentioned above, check the box here AND the relevant box immediately below.)

...Meta-analysis or systematic review

...Other type of research, specify type:

...In-progress research without results (e.g., RCT methodology paper)

...Guideline or consensus statement

...Can't tell

... All other not covered above (ie, non-research, such as letter, editorial or unsystematic review)

5. Do you think this article will need to be cloned for the next level of extraction?

Yes, it reports on two or more separate RCTS, quasi-RCTs, or observational studies (but is NOT a meta-analysis or review)

Yes, it has more than one intervention arm

Yes, for other reasons, specify:

6. For an article that will NOT otherwise proceed to full review (ie, those above that are NOT RCTs, observational studies, or case series/reports), is there any special reason why it should undergo further review (e.g., there is a study embedded in a letter to editor)?

Yes, specify why:

7. For an article that will not otherwise proceed to full review, does this article contain important information not otherwise captured on this form?

Yes, specify:

8. Do you have any other comments?

Yes

Level 3. Full Text Data Abstraction Form (Study Information and Quality Assessment)

1. Should this article undergo full text review at Level 3?

Yes

No

2. Where did the study take place? (check all that apply)

U.S., specify city, state

U.S. military warzone

Outside of the U.S., specify country or region

Not reported or unclear

3. What was the source of funding for the entire study (check all that apply)

Novo Nordisk®

Other Industry

Government

Foundation

Other

None

Not applicable (e.g. case report or registry)

Not reported or unclear

4. Did Novo Nordisk support any other aspect of this study (such as registry, personnel)? For personnel, specify the nature of the relationship/support with Novo Nordisk in the appropriate text box(es)

Statistician

Other Author(s)

Member of the “study group,” “research team,” or similar designation (and NOT an author on the byline of the paper)

Registry

Other, specify

5. Was the number of enrolling centers reported?

1 center

>1 center

Not reported or unclear

Not applicable (e.g. case report or registry)

6. When did the study take place? Specify as a range in months and years, if given. Leave blank, if unclear.

--

7. Is this a registry study?

Yes

If this is CASE REPORT/SERIES or REGISTRY study (e.g. any non-comparative study), STOP HERE.

8. What was the maximum length of consistent follow-up (ie, follow-up performed/attempted to be performed for all patients)?

Number of days (or specify other unit (e.g., hours), if different than days)

Not reported or Unclear

Not applicable (e.g. a retrospective study)

9. Was informed consent obtained? (check all that apply)

Obtained from patient or legal representative (e.g., parents for minors)

Determined to not be required by relevant IRB, Ethics Committee, or equivalent

Not obtained for other reason, specify

Not reported or Unclear

Not applicable (e.g. most retrospective studies)

10. Was Institutional Review Board approval (or equivalent) obtained?

Yes

Was determined to not be required, give brief explanation

Not reported or unclear

If this is NOT a RCT/QUASI-RCT, SKIP to Q#13.

11. Were **providers** blinded to intervention/treatment allocation (as best you can tell from the description in the article)?

Yes (e.g., article describes placebo injections of identical volume and appearance to treatment injection being given at the same time during treatment)

Partially (e.g., article describes “blinded” treatment and placebo injections but does not provide any other information)

No

Not reported or unclear

12. Were **patients** blinded to intervention/treatment allocation (as best you can tell from the description in the article)?

Yes (e.g., article describes placebo injections of identical volume and appearance to treatment injection being given at the same time during treatment)

Partially (e.g., article describes “blinded” treatment and placebo injections but does not provide any other information)

No

Not reported or unclear

13. Were **outcomes assessors** blinded to intervention/treatment allocation (as best you can tell from the description in the article)?

Yes

Partially (e.g., article states that assessors had no access to patient names or identifying information)

No

Not reported or unclear

14. Did the study assess the success of blinding in any way?

Yes, specify

15. Were any of the following explicitly defined a priori? NOTE: Must be EXPLICITLY defined in the methods section as chosen/performed at the outset of the study to qualify as being defined as a priori. Refer to L3 GUIDELINES for term codes.

Primary outcome(s), specify:

Secondary outcome(s)

Thromboembolic harms and/or mortality outcome(s), specify:

Other harms outcome(s), specify:

Sample size calculation

Statistical analyses

16. Were the data collected prospectively for this study?
 Yes, all data were collected prospectively
 Partially, data were collected both prospectively and retrospectively
 No
 Not reported or unclear
 Not applicable (e.g. retrospective case control study)

17. Were any of the following built into the study design? (check all that apply)
 Interim analyses
 Stopping rules

18. Are you concerned that statistical tests were applied or reported inappropriately? If so, explain why.
 Yes, runs multiple analyses without correction (e.g. Bonferroni correction)
 Other, explain

19. Were multivariate analyses performed to control for confounding factors?
 Yes

20. **FOR COMPARATIVE OBSERVATIONAL STUDIES ONLY (RCTs skip to 21).** Did the study make any attempt to match the control group with the intervention group?
 Yes, describe
 No
 Not Necessary, explain

21. Are you concerned about the potential introduction of bias or lack of generalizability of the study? If so, select all potential problem areas that apply and specify reason. REFER to L3 GUIDELINES for instructions and codes.
 Control and intervention groups were not appropriately matched at baseline (e.g. significantly different demographic or comorbidities between the two groups at baseline, REFER to L3 GUIDELINES), specify
 Control and intervention groups received differential treatment(s), besides rFVIIa
 Differential follow-up time between the control and intervention group, specify
 Problem with withdrawals, loss to follow-up, or other missing data, specify
 Other reason, specify

For RCTs/QUASI-RCTs, skip to Q24

COMPARATIVE OBSERVATIONAL STUDIES

22. Was the control group contemporaneous or historical?
 Contemporaneous
 Historical

23. **FOR COMPARATIVE OBSERVATIONAL STUDIES, THIS IS THE LAST QUESTION ON THIS FORM.** Do you have any other comments?
 Yes

RCTs/QUASI-RCTs

24. If the unit of randomization was not the patient, specify the unit here.

Other, specify

25. Was the method of sequence generation for randomization specified? If so, do you have any concerns (explain concerns in text box)?

Yes, was specified, and I have NO CONCERNS

Yes, was specified, but I HAVE CONCERNS, describe

No, was not specified

26. Was the method of allocation concealment described and appropriate?

Yes, it was both described and appropriate (e.g. opaque, sealed envelope)

It was described but was NOT appropriate (e.g., patient name but no other identifying information removed from chart)

No, it was not described

Not applicable

27. If unit of analysis differed from unit of treatment allocation (e.g., providers were randomized, but analyses were of patient outcomes), did authors acknowledge this issue and make appropriate adjustments or conduct sensitivity analyses?

Yes

No

Not applicable (unit of analysis did not differ from unit of treatment allocation)

28. Were analyses performed according to intention-to-treat?

Yes, explicitly stated

Yes, can be inferred (e.g., article states all patients received assigned treatment and follow-up data are available for all patients)

No

Not reported or unclear

29. Skip this question if analyses **were** performed according to intention-to-treat. But, if analyses were NOT performed according to intention-to-treat, give the following information (check all that apply):

Sensitivity analyses were performed

An explanation for why analyses were not performed according to intention-to-treat was given and is summarized here:

30. **FOR RCTs/quasi-RCTs, THIS IS THE LAST QUESTION ON THIS FORM.** Do you have any other comments?

Yes

Level 4. Full Text Article Data Abstraction Form for Intracranial Hemorrhage Studies

INTRACRANIAL HEMORRHAGE

1. Is this a RCT/Quasi-RCT that reports data on intracranial hemorrhage? **If no, STOP ABSTRACTION**

Yes

No

2. Is this a quasi-RCT? If yes, briefly describe details.

Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized/baseline			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check the tick box indicating that:

Brief description

Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols or care by the same cardiac surgery team)

Yes, briefly describe

No

6. rFVIIa Dose Information

rFVIIa Dose	Dose Units (e.g. mg or ug/kg)	Uniform, Mean, or Median Dose? (Use codes U, MN, MD)	SD (or Range or IQR), if applicable	Number of rFVIIa doses	Comments (e.g. specify if variance is range or IQR)

7. Time/Location of rFVIIa administration

Before or at onset of surgery

During surgery, or after, but while still in OR

Postoperatively (e.g. in ICU), but prior to any reoperation

Return from reoperation for bleeding

All other, describe

Not reported or Unclear

Patient demographics and other information

8. If different than number of subjects randomized to each group, specify the number of patients with reported demographic data:

N Intervention	N Control	Comments

Variable	N (or Mean or Median) Intervention	SD (or Range or IQR) Intervention	N (or Mean or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
9. Age					
10. Gender					
11. Admission INR					
12. Hematoma volume on baseline head CT					
13. Time of rFVIIa administration in relation to time of <i>bleed onset</i>					
14. Time of rFVIIa administration in relation to time of baseline head CT					
15. Systolic blood pressure					
16. Other demographic 1, specify					
17. Other demographic 2, specify					
18. Other demographic 3, specify					
19. Other demographic 4, specify					
20. Other demographic 5, specify					

21. If different than number of subjects randomized to each group, specify the number of patients with reported baseline data:

N Intervention	N Control	Comments

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
22. Presence of intraventricular hemorrhage on baseline head CT			
23. History of thrombotic/embolic events, specify			
24. Other comorbidity 1, specify			
25. Other comorbidity 2, specify			
26. Other comorbidity 3, specify			
27. Other comorbidity 4, specify			
28. Other comorbidity 5, specify			

Results

29. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
30. Change in hematoma volume from baseline head CT						
31. Other result 1, specify						
32. Other result 2, specify						
33. Other result 3, specify						
34. Other result 4, specify						
35. Other result 5, specify						
36. Other result 6, specify						
37. Other result 7, specify						
38. Other result 8, specify						

Event	N Intervention	N Control	Comments (e.g. specify other variable)
39. Mortality			
40. Functional status/disability			
41. Other result 9, specify			
42. Other result 10, specify			
43. Other result 11, specify			
44. Other result 12, specify			
45. Other result 13, specify			
46. Other result 14, specify			
47. Other result 15, specify			
48. Other result 16, specify			

Harm information

49. Were harms measured?

No. If checked here, stop abstraction

50. How were harms identified?

Prospectively, describe

Retrospectively, describe

Both prospectively and retrospectively

Not reported or Unclear

51. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?

Yes, specify how

--

52. If harms were adjudicated in any way, specify how.

Blinded panel

Other

--

53. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	N Control	Comments

Undifferentiated Thromboembolic Harms (i.e.)

	Total events (n)	N Intervention	N Control	Comments
54. All thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
55. All arterial thromboembolic events (<i>without further delineation</i>)				
56. Myocardial Infarction				
57. Stroke				
58. Mesenteric thrombosis				
59. Renal infarct				
60. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
61. All venous thromboembolic events (<i>without further delineation</i>)				
62. Pulmonary embolism				
63. Deep vein thrombosis				
64. Mesenteric vein thrombosis				
65. Portal vein thrombosis				
66. Thrombosis in right-side chamber of heart				
67. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
68. All instrument-related thromboembolic events (<i>without further delineation</i>)				
69. ECMO-related thromboembolic events				
70. Arterial line clot				
71. Venous line clot				
72. Other instrument-related thromboembolic event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
73. Multi-organ failure				
74. Cardiogenic shock/need for balloon pump				
75. Respiratory failure/ARDS				
76. Renal failure				
77. Sepsis				
78. DIC				
79. Other event #1, specify				

80. Other event #2, specify				
81. Other event #3, specify				
82. Other event #4, specify				
83. Other event #5, specify				

84. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

Level 4. Full Text Article Data Abstraction Form for Traumatic Bleeding Studies

TRAUMA

1. Is this a RCT/Quasi-RCT that reports data on trauma? **If no, STOP ABSTRACTION**

Yes

No

2. Is this a quasi-RCT? If yes, briefly describe details.

Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check the tick box indicating that.

Brief description

Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols or care by the same cardiac surgery team)

Yes, briefly describe

No

6. **What types of trauma are included in this arm of the study?**

Blunt trauma

Penetrating trauma

Traumatic brain injury

Other, specify

7. **rFVIIa Dose Information**

rFVIIa Dose	Dose Units (e.g. mg or ug/kg)	Uniform, Mean, or Median Dose? (use codes U, MN, MD)	SD (or Range or IQR), if applicable	Number of rFVIIa doses	Comments (e.g. specify if variance is range or IQR)

8. Describe the timing and location of rFVIIa administration below:

Patient demographics and other information

9. If different than number of subjects randomized to each group, specify the number of patients with reported demographic data:

N Intervention	N Control	Comments

Variable	N (or Mean or Median) Intervention	SD (or Range or IQR) Intervention	N (or Mean or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
10. Age					
11. Male sex (n)					
12. Weight (or BMI or body surface area, specify units)					
13. Injury Severity Score (ISS)					
14. Other demographic 1, specify					
15. Other demographic 2, specify					
16. Other demographic 3, specify					

17. If different than the number of subjects randomized to each group, specify the number of patients with reported baseline data:

N Intervention	N Control	Comments

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
18. Acidosis			
19. Abnormal INR			
20. Other comorbidity 1, specify			
21. Other comorbidity 2, specify			
22. Other comorbidity 3, specify			

Results

23. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Continuous variable

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
24. RBCs transfused in 24h (packed units)						
25. FFP transfused						
26. ICU time (days)						
27. Change in intracranial hematoma volume (mL)						
28. Other result 1, specify						
29. Other result 2, specify						

Categorical variable

Event	N Intervention	N Control	Comments (e.g. specify other variable)
30. Mortality within 24h			
31. Mortality within 30d			
32. Number of patients requiring transfusions, specify			
33. Need for return to OR/surgical re-exploration			
34. Other result 3, specify			
35. Other result 4, specify			

Harm information

36. Were harms measured?
No. If checked here, STOP abstraction

37. How were harms identified?
Prospectively, describe
Retrospectively, describe
Both prospectively and retrospectively
Not reported or Unclear

38. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?
Yes, specify how

--

39. If harms were adjudicated in any way, specify how.
Blinded panel
Other

--

40. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	N Control	Comments

Undifferentiated Thromboembolic Harms (i.e.)

	Total events (n)	N Intervention	N Control	Comments
41. All thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
42. All arterial thromboembolic events (without further delineation)				
43. Myocardial Infarction				
44. Stroke				
45. Mesenteric thrombosis				
46. Renal infarct				
47. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
48. All venous thromboembolic events (without further delineation)				
49. Pulmonary embolism				
50. Deep vein thrombosis				
51. Mesenteric vein thrombosis				
52. Portal vein thrombosis				
53. Thrombosis in right-side chamber of heart				
54. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
55. All instrument-related thromboembolic events (without further delineation)				
56. ECMO-related thromboembolic events				
57. Arterial line clot				
58. Venous line clot				
59. Other instrument-related event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
60. Multi-organ failure				
61. Cardiogenic shock/requirement for balloon pump				
62. Respiratory failure/ARDS				
63. Renal failure				
64. Sepsis				
65. DIC				
66. Other event #1, specify				
67. Other event #2, specify				
68. Other event #3, specify				
69. Other event #4, specify				
70. Other event #5, specify				

71. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

--

Level 4. Full Text Article Data Abstraction Form for Liver Transplantation Studies

LIVER TRANSPLANT

1. Is this a RCT/Quasi-RCT that reports data on liver transplant? **If no, STOP ABSTRACTION.**

Yes

No

2. Is this a quasi-RCT? If yes, briefly describe details.

Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized/baseline			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check the tick box indicating that:

Brief description

Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols)

Yes, briefly describe

No

6. Special type(s) of surgery performed (check all that apply)

Multiorgan transplantation, specify

Other, specify

7. rFVIIa Dose Information

Be sure to indicate in the comments box whether administration of rFVIIa was for preventive or emergent reasons

rFVIIa Dose	Dose Units (e.g. mg or ug/kg)	Uniform, Mean, or Median Dose? (Use codes U, MN, MD)	SD (or Range or IQR), if applicable	Number of rFVIIa doses	Comments (e.g. specify if variance is range or IQR)

8. Time/Location of rFVIIa administration

Before or at onset of surgery

During surgery, or after, but while still in OR

Postoperatively (e.g. in ICU), but prior to any reoperation

Return from reoperation for bleeding

All other, describe
Not reported or Unclear

Patient demographics and other information

9. If different than number of subjects randomized to each group, specify the number of patients with reported demographic data:

N Intervention	N Control	Comments

Variable	N (or Mean or Median) Intervention	SD (or Range or IQR) Intervention	N (or Mean or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
10. Age					
11. Gender					
12. Weight (or BMI or body surface area; specify units)					
13. Meld score (or Child Pugh classification)					
14. INR					
15. Warm ischemia at time of donor liver					
16. Cold ischemia at time of donor liver					
17. Other demographic 1, specify					
18. Other demographic 2, specify					
19. Other demographic 3, specify					
20. Other demographic 4, specify					

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
21. Emergency surgery (e.g. fulminant liver failure)			
22. Prior liver transplantation of other major liver surgery			
23. Presence of multiorgan failure			
24. History of thrombotic/embolic event, specify			
25. Diabetes			
26. Renal failure			
27. CHF			
28. COPD			
29. Hypertension			
30. Other comorbidity 1, specify			
31. Other comorbidity 2, specify			
32. Other comorbidity 3, specify			

Results

33. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
34. RBCs transfused (packed units)						
35. FFP transfused						
36. Blood loss (or chest tube drainage) (mLs)						
37. OR time (hours)						
38. Other result 1, specify						
39. Other result 2, specify						

Event	N Intervention	N Control	Comments (e.g. specify other variable)
40. In-hospital mortality, specify			
41. Number of patients requiring transfusion, specify			
42. Need for re-operation or re-transplantation			
43. Other result 3, specify			
44. Other result 4, specify			

Harm information

45. Were harms measured?

No. If checked here, stop abstraction

46. Was there an explicit follow up time set for determination of harms?

Yes, describe

47. How were harms identified?

Prospectively, describe

Retrospectively, describe

Both prospectively and retrospectively

Not reported or Unclear

48. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?

Yes, specify how

49. If harms were adjudicated in any way, specify how.

Blinded panel

Other

50. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	N Control	Comments

Undifferentiated Thromboembolic Harms (i.e.)

	Total events (n)	N Intervention	N Control	Comments
51. All thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
52. All arterial thromboembolic events (<i>without further delineation</i>)				
53. Myocardial Infarction				
54. Stroke				
55. Mesenteric thrombosis				
56. Renal infarct				
57. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
58. All venous thromboembolic events (<i>without further delineation</i>)				
59. Pulmonary embolism				
60. Deep vein thrombosis				
61. Mesenteric vein thrombosis				
62. Portal vein thrombosis				
63. Thrombosis in right-side chamber of heart				
64. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
65. All instrument-related thromboembolic events (<i>without further delineation</i>)				
66. ECMO-related thromboembolic events				
67. Arterial line clot				
68. Venous line clot				
69. Other instrument-related thromboembolic event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
70. Multi-organ failure				
71. Cardiogenic shock/need for balloon pump				
72. Respiratory failure/ARDS				
73. Renal failure				
74. Sepsis				
75. DIC				

76. Other event #1, specify				
77. Other event #2, specify				
78. Other event #3, specify				
79. Other event #4, specify				
80. Other event #5, specify				

81. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

Level 4. Full Text Article Data Abstraction Form for Cardiac Surgery Studies

CARDIAC SURGERY

1. Is this a RCT/Quasi-RCT that reports data on cardiac surgery? **If no, STOP ABSTRACTION**

Yes

No

2. Is this a quasi-RCT? If yes, briefly describe details.

Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check the tick box indicating that.

Brief description

Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols or care by the same cardiac surgery team)

Yes, briefly describe

No

6. **Type (s) of surgery performed (for adults) (check all that apply)**

Multiple surgeries

CABG

Cardiac transplantation

Single valve repair/replacement

Any aortic

All Other, specify

No cardiac surgery for adults

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

7. **Type (s) of surgery performed (for child) (check all that apply)**

Reoperation (any type)

Correction of congenital heart disease

All other, specify

No surgery performed in child

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

8. **rFVIIa Dose Information**

rFVIIa Dose	Dose Units (e.g. mg or ug/kg)	Uniform, Mean, or Median Dose? (use codes U, MN, MD)	SD (or Range or IQR), if applicable	Number of rFVIIa doses	Comments (e.g. specify if variance is range or IQR)

- 9. Time/Location of rFVIIa administration
- Before or at onset of surgery
- During surgery, or after, but while still in OR
- Postoperatively (e.g. in ICU), but prior to any reoperation
- Return from reoperation for bleeding
- All other, describe
- Not reported or Unclear

Patient demographics and other information

10. If different than number of subjects randomized to each group, specify the number of patients with reported demographic/baseline data:

N Intervention	N Control	Comments

Variable	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
11. Age					
12. Gender					
13. Weight (or BMI or body surface area, specify units)					
14. Other demographic 1, specify					
15. Other demographic 2, specify					
16. Other demographic 3, specify					
17. Other demographic 4, specify					

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
18. Emergency surgery			
19. Previous cardiac surgery			
20. History of thrombotic/embolic events, specify			
21. Diabetes			
22. Renal failure			
23. CHF			
24. COPD			
25. Hypertension			
26. Other comorbidity 1, specify			
27. Other comorbidity 2, specify			
28. Other comorbidity 3, specify			

Results

29. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Continuous variable

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
30. RBCs transfused in 24h (packed units)						
31. FFP transfused						
32. Blood loss (or chest tube drainage) (mLs)						
33. OR time (hours)						
34. Other result 1, specify						
35. Other result 2, specify						
36. Other result 3, specify						
37. Other result 4, specify						
38. Other result 5, specify						
39. Other result 6, specify						

Results categorical variables

Event	N Intervention	N Control	Comments (e.g. specify other variable)
40. In-hospital mortality			
41. Need for return to OR/surgical re-exploration			
42. Number of patients requiring transfusions, specify further			
43. Other result 7, specify			
44. Other result 8, specify			
45. Other result 9, specify			
46. Other result 10, specify			
47. Other result 11, specify			
48. Other result 12, specify			

Harm information

49. Were harms measured?

No. If checked here, STOP abstraction

50. Was there an explicit follow up time for determination of harms?

Yes, describe

51. How were harms identified?

Prospectively, describe

Retrospectively, describe

Both prospectively and retrospectively

Not reported or Unclear

52. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?

Yes, specify how

53. If harms were adjudicated in any way, specify how.

Blinded panel

Other

54. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	N Control	Comments

Undifferentiated Thromboembolic Harms (i.e.)

	Total events (n)	N Intervention	N Control	Comments
55. All thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
56. All arterial thromboembolic events (without further delineation)				
57. Myocardial Infarction				
58. Stroke				
59. Mesenteric thrombosis				
60. Renal infarct				
61. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
62. All venous thromboembolic events (without further delineation)				
63. Pulmonary embolism				
64. Deep vein thrombosis				
65. Mesenteric vein thrombosis				
66. Portal vein thrombosis				
67. Thrombosis in right-side chamber of heart				
68. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
69. All instrument-related thromboembolic events (without further delineation)				
70. ECMO-related thromboembolic events				
71. Arterial line clot				

72. Venous line clot				
73. Other instrument-related event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
74. Multi-organ failure				
75. Cardiogenic shock/requirement for balloon pump				
76. Respiratory failure/ARDS				
77. Renal failure				
78. Sepsis				
79. DIC				
80. Other event #1, specify				
81. Other event #2, specify				
82. Other event #3, specify				
83. Other event #4, specify				
84. Other event #5, specify				

85. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

--

Level 4. Full Text Article Data Abstraction Form for Prostatectomy Studies

PROSTATECTOMY

1. Is this a RCT/Quasi-RCT that reports data on prostatectomy? **If no, STOP ABSTRACTION.**

Yes

No

Study characteristics

2. Is this a quasi-RCT? If yes, briefly describe details.

Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized/baseline			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check the tick box indicating that:

Brief description

Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols)

Yes, briefly describe

No

6. Type (s) of surgery performed (check all that apply)

Radial retropubic prostatectomy

Millin prostatectomy

All other, specify

7. rFVIIa Dose Information

Indicate in the comments box whether administration of rFVIIa was for preventive or emergent reasons.

rFVIIa Dose	Dose Units (e.g. mg or ug/kg)	Uniform, Mean, or Median Dose? (Use codes U, MN, MD)	SD (or Range or IQR), if applicable	Number of rFVIIa doses	Comments (e.g. specify if variance is range or IQR)

8. Time/Location of rFVIIa administration

Before or at onset of surgery

During surgery, or after, but while still in OR

Postoperatively (e.g. in ICU), but prior to any reoperation

Return from reoperation for bleeding

All other, describe

Not reported or Unclear

Patient demographics and other information

9. If different than number of subjects randomized to each group, specify the number of patients with reported demographic/baseline data:

N Intervention	N Control	Comments

Variable	N (or Mean or Median) Intervention	SD (or Range or IQR) Intervention	N (or Mean or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
10. Age					
11. Gender					
12. Weight (or BMI or body surface area; specify units)					
13. Other demographic 1, specify					
14. Other demographic 2, specify					
15. Other demographic 3, specify					
16. Other demographic 4, specify					

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
17. History of thrombotic/embolic events, specify			
18. Emergency surgery			
19. Diabetes			
20. Renal failure			
21. CHF			
22. COPD			
23. Hypertension			
24. Other comorbidity 1, specify			
25. Other comorbidity 2, specify			
26. Other comorbidity 3, specify			

Results

27. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
28. RBCs transfused (packed units)						
29. FFP transfused						
30. Blood loss (or chest tube drainage) (mLs)						

31. OR time (hours)						
32. Length of hospital stay (days)						
33. Other result 1, specify						
34. Other result 2, specify						

Event	N Intervention	N Control	Comments (e.g. specify other variable)
35. In-hospital mortality			
36. Number of patients requiring transfusions, specify			
37. Need for re-operation or re-transplantation			
38. Other result 3, specify			
39. Other result 4, specify			

Harm information

40. Were harms measured?

No. If checked here, stop abstraction

41. Was there an explicit follow up time set for determination of harms

Yes, describe

42. How were harms identified?

Prospectively, describe

Retrospectively, describe

Both prospectively and retrospectively

Not reported or Unclear

43. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?

Yes, specify how

44. If harms were adjudicated in any way, specify how.

Blinded panel

Other

45. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	N Control	Comments

Undifferentiated Thromboembolic Harms (i.e.)

	Total events (n)	N Intervention	N Control	Comments
46. All thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
47. All arterial thromboembolic events (without further delineation)				
48. Myocardial Infarction				

49. Stroke				
50. Mesenteric thrombosis				
51. Renal infarct				
52. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
53. All venous thromboembolic events (without further delineation)				
54. Pulmonary embolism				
55. Deep vein thrombosis				
56. Mesenteric vein thrombosis				
57. Portal vein thrombosis				
58. Thrombosis in right-side chamber of heart				
59. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
60. All instrument-related thromboembolic events (without further delineation)				
61. ECMO-related thromboembolic events				
62. Arterial line clot				
63. Venous line clot				
64. Other instrument-related thromboembolic event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
65. Multi-organ failure				
66. Cardiogenic shock/need for balloon pump				
67. Respiratory failure/ARDS				
68. Renal failure				
69. Sepsis				
70. DIC				
71. Other event #1, specify				
72. Other event #2, specify				
73. Other event #3, specify				
74. Other event #4, specify				
75. Other event #5, specify				

76. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

Appendix F. Strength of Evidence and Applicability Assessment Forms

Assessment form for: * Clinical Domain of: [_____]

* Outcome(s) of: [_____]

Outcome of Interest	Number of Studies	Number of Subjects		Domains Pertaining to Strength of Evidence						Estimated Magnitude of Effect	Effect of rFVIIa Dosage	Overall Strength of Evidence Grade
		rFVIIa	Usual Care	Risk of Bias Domains			Consistency	Directness	Precision			
				Design	Quality	Summary Risk of Bias*						
1.				RCTs								
				Comp Obs								
2.				RCTs								
				Comp Obs								
3.				RCTs								
				Comp Obs								
4.				RCTs								
				Comp Obs								
5.				RCTs								
				Comp Obs								

RCT, randomized controlled trial; Comp Obs, comparative observational study; SOE, strength of evidence.

*For further details on assigning a summary risk score, see guidance document.