OSTEOPOROSIS/BONE MINERAL DENSITY – PUBMED SEARCH METHODOLOGY

DATABASE SEARCHED& TIME PERIOD COVERED:
PubMed – 1966-2005

OTHER LIMITERS:
ENGLISH
HUMAN

SEARCH STRATEGIES:

SEARCH #1a (Specified bisphosphonates)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
alendronate* OR fosamax (860)
OR
resindronate* OR actonel (174)
OR
etidronate* OR didronel (623)
OR
ibandronate* OR boniva (93)
OR
pamidronate* OR aredia (412)
OR
zoledronic acid OR zometa (112)
OR
droloxifene* (13)

TOTAL OF ABOVE SEARCHES – DUPLICATES ELIMINATED: **1757**

SEARCH #1b (Other bisphosphonates)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
bisphosphonate*
NOT
Results of Search #1a

TOTAL NUMBER OF ITEMS: 687

SEARCH #2a (Specified SERMs)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
raloxifene* OR evista (560)
tamoxifen* OR nolvadex OR emblon OR fentamox OR soltamox OR tamofen (697)

TOTAL OF ABOVE SEARCHES – DUPLICATES ELIMINATED: 784

SEARCH #2b (Other SERMs)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
selective estrogen receptor modulators OR serm OR serms
NOT
Results of Search #2a

TOTAL NUMBER OF ITEMS: 186

SEARCH #3 (Calcitonin)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
calcitonin* OR miacalcin OR calcimar OR cibacalcin
NOT
pth OR parathyroid hormone

TOTAL NUMBER OF ITEMS: 1078

SEARCH #4 (PTH)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
pth OR parathyroid hormone

TOTAL NUMBER OF ITEMS: 3787

SEARCH #5 (Teriparatide)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
teriparatide OR forteo

TOTAL NUMBER OF ITEMS: 182

SEARCH #6 (Exercise)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
(exercise[mh] OR exercis*[ti] OR physical fitness OR physically fit OR physical activity)
NOT
Results of previous searches

TOTAL NUMBER OF ITEMS: 2832

SEARCH #7 (Letrozole)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
letrozole OR femora
NOT
Results of previous searches

TOTAL NUMBER OF ITEMS: 356

SEARCH #8 (AMG 162)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
amg162 OR amg 162

TOTAL NUMBER OF ITEMS: 2

SEARCH #9 (**Ospemifene)**
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
ospemifene*

TOTAL NUMBER OF ITEMS: 6

SEARCH #10 (Strontium ralenate)

osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
strontium ralenate*
NOT
Results of previous searches

TOTAL NUMBER OF ITEMS: 167

SEARCH #11(Testosterone)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
testosterone

TOTAL NUMBER OF ITEMS: 904

SEARCH #12 (**Tiludronate**)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
tiludronate OR skelid

TOTAL NUMBER OF ITEMS: 38

SEARCH #13 (Toremifene)
osteoporosis or osteopenia or osteopaenia or fracture* or bone mineral OR fractures[mh] OR bone density
AND
toremifene*
TOTAL NUMBER OF ITEMS: 27

OSTEOPOROSIS/OSTEOPENIA & THERAPIES – SEARCH METHODOLOGY

DATABASE:
EBM Reviews On OVID (Cochrane Database of Systematic Reviews, DARE, Controlled Trials Register, and ACP Journal Club databases)

DATE LIMITERS – None

SEARCH STRATEGY:
NOTE: "mp." is a group field indicator in OVID. The fields searched are:
Title, Short Title, Abstract, Text Word, Keyword, Heading Word, Caption Text, MESH heading

osteoporosis or osteopenia or osteopaenia or fracture$ or bone mineral.mp.
AND
bisphosphonate$.mp. **258**
alendronate$ or fosamax.mp. **294**
resindronate$ or actonel.mp. **1**
etidronate$ or didronel.mp. **153**
ibandronate$ or boniva.mp. **35**
pamidronate$ or aredia.mp. **105**
zoledronic acid$ or zometa.mp. **19**
selective estrogen receptor modulator$ or serm$.mp. **108**
raloxifene or evista.mp. **141**
tamoxifen or nolvadex or emblon or fentamox or soltamox or tamofen.mp. **80**
droloxifene.mp. **1**
calcitonin$ or miacalcin or calcimar or cibacalcin.mp. **311**
parathyroid hormone$ or pth.mp. **366**
teriparatide or forteo.mp. **26**
exercis$.mp. and (calcium or vitamin d).mp. **140**

ALL RECORDS WERE IMPORTED INTO PROCITE AND DUPLICATES WERE REMOVED. TOTAL NUMBER OF UNIQUE ITEMS: 1390

Evidence-based Practice Center
Bone Density Screening Form

FINAL 10-25-05

Article ID: _____

First Author: _____
(Last name of first author)

Reviewer: _____

1. Does this study include humans?
   - Yes 1
   - No ..... 2 **(STOP)**

2. Intervention(s) studied: **(Check all that apply)**
   - Alendronate (Fosamax) ..... ❒
   - AMG 162 ..... ❒
   - Calcitonin (Miacalcin) ..... ❒
   - Estrogen ..... ❒
   - Etidronate (Didronel) ..... ❒
   - Ibandronate (Boniva) ..... ❒
   - Pamidronate (Aredia) (APD) ..... ❒
   - PTH (Teriparatide) (Forteo) (Preos) ..... ❒
   - Raloxifine (Evista) ..... ❒
   - Risedronate (Actonel) ..... ❒
   - Tamoxifen ..... ❒
   - Testosterone ..... ❒
   - Zoledronic acid (Zometa) ..... ❒
   - None of the above ..... ❒ **(STOP)**

3. What is the focus of the article: **(Circle one)**
   - Efficacy 1
   - Safety/adverse events 2
   - Both 3
   - Neither 4

4. Condition(s) studied: **(Check all that apply)**
   - Fracture prevention ..... ❒
   - Osteopenia ..... ❒
   - Osteoporosis ..... ❒
   - Osteoporosis prevention ..... ❒
   - None of the above ..... ❒ **(STOP)**

5. Is the study part of a named trial?
   - No 1
   - Yes 2

   If yes, specify trial name:

   _____

6. Study design: **(Circle one)**
   - Descriptive (historical, editorial, etc.) ..... 1 **(STOP)**
   - Review/meta-analysis ..... 2 **(STOP)**
   - Randomized clinical trial 3
   - Trial with open-label extension 4
   - Controlled clinical trial 5
   - Cohort/case control - 1000+ subjects 6
   - Cohort/case control - under 1000 subjects ..... 7 **(STOP)**
   - Case Report ..... 8 **(STOP)**
   - Other design ..... 9 **(STOP)**

7. Study population: **(Check all that apply)**

   Gender
   - Men ..... ❒
   - Pre-menopausal women ..... ❒
   - Post-menopausal women ..... ❒
   - Women otherwise undefined ..... ❒

   Age
   - Adults (18 and over) ..... ❒
   - Children (under 18) ..... ❒

   Race
   - Non-caucasian ..... ❒

   Other
   - Steroid-induced osteoporosis ..... ❒

8. Which clinical markers are used? **(Check all that apply)**
   - Bone density ..... ❒
   - Bone formation or bone turnover ..... ❒
   - Fractures ..... ❒
   - Stature/height ..... ❒
   - None of the above ..... ❒

9. Does the article need a translator? **(Circle one)**
   - No 1
   - Yes 2

   If YES specify language:

   _____

10. Do you think this article might be a duplicate or include the same data as another study?
    - No 1
    - Yes 2

    If yes, which one(s)? _____
    (Enter article ID, author, or 9999 for "don't know.")

11. Is there a reference that needs to be checked?
    - No 1
    - Yes 2

    If yes, which one(s)?

    _____
    (Enter reference # &/or author, or 9999 for "don't know.")

NOTE:

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 1-3: Article, Setting, Eligibility criteria

Author, Year, Drug, Country, Trial name	Setting, Quality (Jadad score)	Eligibility criteria
Aris RM et al., 2000[1] Pamidronate US	Setting: Single center Jadad: 3	Inclusion criteria: Men, Women otherwise undefined, Organ transplant, Cystic Fibrosis Exclusion criteria: Pregnancy, Renal insufficiency, Life expectancy <5 years, Graft Failure
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	Setting: Multi-center Jadad: 4	Inclusion criteria: Post-menopausal >5 years, Osteoporosis T-score <= -2.5 hip, Osteoporosis T-score <= -2.5 spine Exclusion criteria: Age > 85, Carcinoma or suspected carcinoma, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Malabsorption syndrome, Urolithiasis, Bisphosphonates, Calcitonin, Fluoride, Androgen, Estrogen agonists (including estrogen), Anabolic steroids, Corticoids/Glucocorticoids, Alcohol Abuse, Allergy to PTH, age<30, LS spine abnormalities prohibiting DEXA, previous PTH use
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	Setting: Multi-center Jadad: 4	Inclusion criteria: Post-menopausal women NOS, Osteoporosis T-score <= -2.5 spine, Prior Hysterectomy Exclusion criteria: Cardiovascular disease, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Venous thromboembolic disease - Active, Venous thromboembolic disease - Ever, Bisphosphonates, Calcitonin, Fluoride, Vitamin D deficient, recent major upper GI mucosal erosive disease, Increased risk of breast cancer, Unexplained genital bleeding x 1 year, Fasting triglycerides >400mg/dL, Contraindication to HRT, HRT within last 6 months
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Setting: Multi-center Jadad: 4	Inclusion criteria: Post-menopausal >5 years, Osteoporosis T-score <= -2 spine, Osteoporosis/Fracture Exclusion criteria: Metabolic bone disorder other than osteoporosis, Renal insufficiency, Bisphosphonates, Fluoride, Med known to affect skeleton, Diseases known to affect skeleton, > 2 fractures lumbar spine, Contraindication to Ca or Vitamin D, Hypercalcemia, Hypocalcemia, age <=55, age >= 80, T score<-5.0
Coco M et al., 2003[5] Pamidronate US	Setting: Setting not reported Jadad: 2	Inclusion criteria: Men, Women otherwise undefined, Organ transplant Exclusion criteria: Pregnancy
Cosman F et al., 2001[6] Estrogen, PTH US	Setting: Single center Jadad: 3	Inclusion criteria: Osteoporosis T-score <= -2.5 hip, Osteoporosis T-score <= -2.5 spine, Age >40 Exclusion criteria: Metabolic bone disorder other than osteoporosis, Nephrolithiasis
Cosman F et al., 2005[7] Alendronate, PTH US	Setting: Single center Jadad: 3	Inclusion criteria: Women otherwise undefined, Osteoporosis T-score <= -2 hip, Osteoporosis T-score <= -2.5 spine, T score ,-2.0 plus fracture, Alendronate for at least 1 year Exclusion criteria: Hypothyroidism, Hyperthyroidism, Hyperparathyroidism, Hypoparathroidism, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Nephrolithiasis, Anticonvulsants, Estrogen agonists (including estrogen), Corticoids/Glucocorticoids, Abnormal Urinary Calcium, Abnormal CBC

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Author, Year, Drug, Country, Trial name	Setting, Quality (Jadad score)	Eligibility criteria
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	Setting: Multi-center Jadad: 3	Inclusion criteria: Men, Women otherwise undefined, Osteoporosis score based on t-score and/or fractures and/or radiographic Exclusion criteria: Age > 75, Carcinoma or suspected carcinoma, Cardiovascular disease, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Upper GI, LS spine abnormalities prohibiting DEXA, Med known to affect skeleton, Drug Hypersensitivity, History of Radiotherapy
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	Setting: Setting not reported Jadad: 1	Inclusion criteria: Organ transplant, ambulatory, normal diet Exclusion criteria: Med known to affect skeleton, Hypogonadism
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	Setting: Single center Jadad: 5	Inclusion criteria: Women otherwise undefined, Age > 65 Exclusion criteria: Carcinoma or suspected carcinoma, Hyperthyroidism, Hyperparathyroidism, Hepatic insufficiency, Renal insufficiency, Anticonvulsants, Bisphosphonates, Calcitonin, Hormone use, Corticoids/Glucocorticoids, Med known to affect skeleton, Contraindication to HRT, Contraindication to alendronate, BMD hip T score >0.0
Grotz W et al., 2001[11] Ibandronate Germany	Setting: Single center Jadad: 2	Inclusion criteria: Men, Pre-menopausal women, Post-menopausal women NOS, Organ transplant Exclusion criteria: Kidney Pancreas Transplant
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Setting: Setting not reported Jadad: 3	Inclusion criteria: Women otherwise undefined, Osteopenia T-score <= -1.0 NOS, Primary Billiary Cirrhosis Exclusion criteria: Renal insufficiency, Upper GI, Bisphosphonates, Fluoride, Estrogen agonists (including estrogen), Corticoids/Glucocorticoids, Bilirubin >10mg/dL
Harris ST et al., 2001[13] Estrogen, Resindronate US	Setting: Multi-center Jadad: 2	Inclusion criteria: Post-menopausal >1 year Exclusion criteria: Metabolic bone disorder other than osteoporosis, HRT, Med known to affect skeleton, Major systemic Disease, Abnl Pap, Significant Psychiatric disease, LS spine abnormalities prohibiting DEXA
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	Setting: Setting not reported Jadad: 2	Inclusion criteria: Post-menopausal women NOS, Osteoporosis/Fracture, <7 ETOH/wk Exclusion criteria: Endocrine disease, Metabolic bone disorder other than osteoporosis, Bisphosphonates, Calcitonin, Corticoids/Glucocorticoids
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	Setting: Multi-center Jadad: 1	Inclusion criteria: Post-menopausal >6 months Exclusion criteria: Carcinoma or suspected carcinoma, Renal insufficiency, Upper GI, Bisphosphonates, Calcitonin, Fluoride, HRT, Med known to affect skeleton, phosphate binding antiacid, >60 years

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Author, Year, Drug, Country, Trial name	Setting, Quality (Jadad score)	Eligibility criteria
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	Setting: Multi-center Jadad: 5	Inclusion criteria: Post-menopausal >2 years, Osteoporosis T-score <= -2.5 hip, Osteoporosis T-score <= -2.5 spine, Hip and Spine Dexa <-2.0 Exclusion criteria: Hypothyroidism, Hyperthyroidism, Hyperparathyroidism, Metabolic bone disorder other than osteoporosis, Bisphosphonates, Fluoride, HRT, Estrogen agonists (including estrogen), Corticoids/Glucocorticoids, LS spine abnormalities prohibiting DEXA, Vitamin D deficient, Severe Upper GI Sx, Severe Osteoporosis, age >90, age <60, Abnormal Urinary Calcium
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	Setting: Single center Jadad: 2	Inclusion criteria: Post-menopausal >5 years, Osteoporosis T-score <= -2.5 NOS, Osteoporosis/Fracture, ambulatory Exclusion criteria: Age > 75, Carcinoma or suspected carcinoma, Metabolic bone disorder other than osteoporosis, Med known to affect skeleton, bilateral hip fractures, mental condition that would preclude participation
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	Setting: Multi-center Jadad: 1	Inclusion criteria: Women otherwise undefined, Osteoporosis/Fracture, Back Pain Exclusion criteria: Metabolic bone disorder other than osteoporosis, HRT, Estrogen agonists (including estrogen), Med known to affect skeleton
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	Setting: Setting not reported Jadad: 1	Inclusion criteria: Post-menopausal women NOS, Osteoporosis NOS Exclusion criteria: Metabolic bone disorder other than osteoporosis, HRT, Estrogen agonists (including estrogen), Med known to affect skeleton, any lumbar vertebral fractures
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	Setting: Single center Jadad: 1	Inclusion criteria: Men, Women otherwise undefined, Organ transplant Exclusion criteria: Renal insufficiency, Myeloma
Kim SH et al., 2004[21] Pamidronate Asia	Setting: Single center Jadad: 2	Inclusion criteria: Men, Post-menopausal women NOS, Postmenopausal >18 months Exclusion criteria: Renal insufficiency, Bisphosphonates, bed rest
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	Setting: Multi-center Jadad: 4	Inclusion criteria: Men, Women otherwise undefined, Osteoporosis NOS, age >50, 1-4 vertebral fractures Exclusion criteria: Cardiovascular disease, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Gastrointestinal disease, treatment with residronate or etidronate, Secondary Osteoperosis, radiographic findings that affect vertebral intensity, Med known to affect skeleton, malignancy under treatment with anti-tumor agents, radiation therapy to lumbar spine or pelvis
Lindsay R et al., 1997[23] Estrogen, PTH US	Setting: Single center Jadad: 3	Inclusion criteria: Post-menopausal women NOS, Osteoporosis T-score <= -2.5 NOS, Osteoporosis score based on t-score and/or fractures and/or radiographic, HRT >1 year, Stable Bone Mass >1year Exclusion criteria: Hypothyroidism, Hyperthyroidism, Hepatic insufficiency, Renal insufficiency, Nephrolithiasis, Secondary Osteoperosis

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Author, Year, Drug, Country, Trial name	Setting, Quality (Jadad score)	Eligibility criteria
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Setting: Multi-center Jadad: 1	Inclusion criteria: Post-menopausal >5 years, Osteopenia T-score <= -2.0 NOS, HRT >1 year Exclusion criteria: Hyperthyroidism, Metabolic bone disorder other than osteoporosis, Upper GI, Bisphosphonates, Calcitonin
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	Setting: Multi-center Jadad: 5	Inclusion criteria: Osteoporosis T-score <= -2 hip, Osteoporosis T-score <= -2 spine, Postmenopausal >18 months, Age >40, Age>25 if surgical menopause, Good health Exclusion criteria: Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Upper GI, Venous thromboembolic disease - Active, Venous thromboembolic disease - Ever, Bisphosphonates, Fluoride, Estrogen agonists (including estrogen), SERMS, Anabolic steroids, Corticoids/Glucocorticoids, LS spine abnormalities prohibiting DEXA, Immunosuppressants, Hypocalcemia, previous PTH use, Med known to affect skeleton, Breast Cancer, Uterine Cancer
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Setting: Setting not reported Jadad: 1	Inclusion criteria: Women otherwise undefined, Osteoporosis NOS Exclusion criteria: NR
Ninkovic M et al., 2002[27] Pamidronate UK	Setting: Setting not reported Jadad: 2	Inclusion criteria: Organ transplant Exclusion criteria: Renal insufficiency, Bisphosphonates, retransplantation
Ravn P et al., 1996[28] Ibandronate Western Europe	Setting: Single center Jadad: 3	Inclusion criteria: Post-menopausal >5 years, 816, 817 Exclusion criteria: Age > 75, Bisphosphonates, Calcitonin, HRT, Diseases, conditions or treatments known to interfere with calcium metab
Recker R et al., 2004[29] Ibandronate US, Western Europe	Setting: Multi-center Jadad: 3	Inclusion criteria: Post-menopausal >5 years, Osteoporosis T-score <= -2 spine, Osteoporosis/Fracture Exclusion criteria: Carcinoma or suspected carcinoma, Hypothyroidism, Hyperthyroidism, Hyperparathyroidism, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Gastrointestinal disease, Bisphosphonates, Calcitonin, Fluoride, HRT, Corticoids/Glucocorticoids, Alcohol Abuse, Med known to affect skeleton, Hypercalcemia, Hypocalcemia, Contraindication to Ca or Vitamin D, Cyclosporine
Reid IR et al., 1994[30] Pamidronate Australia/NZ	Setting: Single center Jadad: 4	Inclusion criteria: Post-menopausal women NOS, Osteoporosis/Fracture Exclusion criteria: Hypothyroidism, Hyperthyroidism, Hepatic insufficiency, Renal insufficiency, Anticonvulsants, Bisphosphonates, Calcitonin, Fluoride, HRT, Anabolic steroids, Corticoids/Glucocorticoids, Major systemic Disease, Hypercalcemia, Hypocalcemia

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Author, Year, Drug, Country, Trial name	Setting, Quality (Jadad score)	Eligibility criteria
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	Setting: Multi-center Jadad: 3	Inclusion criteria: Post-menopausal >5 years, Osteoporosis T-score <= -2 spine Exclusion criteria: Carcinoma or suspected carcinoma, Hypothyroidism, Hyperthyroidism, Hyperparathyroidism, Hypoparathroidism, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Bisphosphonates, Fluoride, HRT, Estrogen agonists (including estrogen), >1 Fracture, Vitamin D deficient, Med known to affect skeleton
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	Setting: Multi-center Jadad: 2	Inclusion criteria: Post-menopausal women NOS, 501, hysterectomy <15 years prior Exclusion criteria: Hepatic insufficiency, Renal insufficiency, Venous thromboembolic disease - Ever, Anticonvulsants, Bisphosphonates, Calcitonin, Fluoride, Androgen, Estrogen agonists (including estrogen), Progestin, Lipid lowering agents, Vitamin D, Corticoids/Glucocorticoids, age <40, Endocrine disease requiring tx except thyroid, FSH<40, >4 drinks EtOH/day, >60 years, Breast Cancer, Estrogen Dependent CA, Any cancer except skin in last 5 years, Serious postmenopausal symptoms
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	Setting: Multi-center Jadad: 4	Inclusion criteria: Post-menopausal >6 months, Osteopenia T-score <= -2.0 NOS, Spine/Hip anatomy suitable for Dexa Exclusion criteria: Metabolic bone disorder other than osteoporosis, Upper GI, Bisphosphonates, Fluoride, HRT, Estrogen agonists (including estrogen), Anabolic steroids, Corticoids/Glucocorticoids, Immunosuppressants, previous PTH use, Inability to remain 30min upright, Vitamin D deficient
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	Setting: Single center Jadad: 3	Inclusion criteria: Post-menopausal women NOS, Osteoporosis T-score <= -2 spine, Osteoporosis/Non-traumatic fracture Exclusion criteria: Metabolic bone disorder other than osteoporosis, Bisphosphonates, Calcitonin, Fluoride, HRT, Anabolic steroids, Corticoids/Glucocorticoids, oopherectomy, Med known to affect skeleton

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 4: Interventions

Author, Year, Drug, Country, Trial name	Interventions (drug, dose, duration)
Aris RM et al., 2000[1] Pamidronate US	Pamidronate 30 mg every 2 weeks vs Control Duration: 24 months
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	Placebo and PTH 40 ug daily vs Placebo and Alendronate 10 mg daily Duration: 14 months
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	Placebo daily vs Placebo and Alendronate 10 mg daily vs Placebo and Estrogen 0.625 mg daily vs Alendronate 10 mg and Estrogen 0.625 mg daily Duration: 24 months
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Placebo daily vs Ibandronate 2.5 mg daily vs Placebo every other day for 12 doses followed by daily for the remainder of 3 and Ibandronate 20 mg every other day for 12 doses every 3 months Duration: 36 months
Coco M et al., 2003[5] Pamidronate US	Placebo vs Pamidronate 60 mg at baseline and Pamidronate 30 mg at months 1, 2, 3 and 6 Duration: 12 months
Cosman F et al., 2001[6] Estrogen, PTH US	Placebo daily vs PTH 400 I.U. daily Duration: 36 months
Cosman F et al., 2005[7] Alendronate, PTH US	Alendronate 70 mg weekly and PTH 25 ug daily vs Alendronate 70 mg weekly and PTH 25 ug daily for 3 months, off 3 months vs Alendronate 70 mg weekly Duration: 15 months
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	Risedronate 2.5 mg daily vs Etidronate 200 mg daily for 14 days every 3 months Duration: 11 months
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	Calcitonin 100 I.U. daily vs Etidronate 400 mg daily for 14 days every 2.5 months vs Vitamin D 32000 I.U. weekly Duration: 18 months
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	Placebo vs Placebo and Estrogen .625 mg daily vs Placebo and Alendronate 10 mg daily vs Alendronate 10 mg and Estrogen .625 mg daily Duration: 36 months
Grotz W et al., 2001[11] Ibandronate Germany	Control vs Ibandronate 1 mg daily for 1 day and Ibandronate 2 mg every 3 months for 9 months
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Etidronate 400 mg daily for 14 days every 3 months vs Alendronate 10 mg daily Duration: 24 months

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 4: Interventions

Author, Year, Drug, Country, Trial name	Interventions (drug, dose, duration)
Harris ST et al., 2001[13] Estrogen, Resindronate US	Placebo and Estrogen 0.625 mg daily vs Estrogen 0.625 mg and Risedronate 5 mg daily Duration: 12 months
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	Placebo and PTH 800 I.U. daily vs Calcitonin 75 I.U. and PTH 800 I.U. daily Duration: variable
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	Placebo daily vs Alendronate 2.5 mg daily vs Alendronate 5 mg daily vs Estrogen dosage variable and Progesterone dosage variable daily Duration: 24 months
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	Placebo daily and Placebo2 dosage not applicable weekly vs Placebo weekly and Risedronate 5 mg daily vs Placebo daily and Alendronate 70 mg weekly Duration: 12 months
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	Control daily vs Estrogen .625 mg daily vs Etidronate 200 mg daily for 2 weeks every 12 weeks vs Calcitonin 20 I.U. weekly vs Vitamin D 1 ug daily vs Vitamin K 45 mg daily Duration: 24 months
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	Etidronate 200 mg daily for 14 days every 3 months vs Alendronate 5 mg daily Duration: 6 months
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	Etidronate 200 mg daily for 14 days every 3 months for 18 months vs Alendronate 5 mg daily for 6 months and Etidronate 200 mg daily for 14 days every 3 months for 12 months
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	Control vs Pamidronate 60 mg Variable Duration: 12 months
Kim SH et al., 2004[21] Pamidronate Asia	Placebo every 3 months vs Pamidronate 30 mg every 3 months Duration: 12 months
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	Placebo daily for 2 weeks every 12 weeks and Risedronate 2.5 mg daily vs Placebo daily and Etidronate 200 mg daily for 2 weeks every 12 weeks Duration: 22 months
Lindsay R et al., 1997[23] Estrogen, PTH US	PTH 400 I.U. daily vs Control Duration: 36 months
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Placebo daily vs Alendronate 10 mg daily Duration: 12 months

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 4: Interventions

Author, Year, Drug, Country, Trial name	Interventions (drug, dose, duration)
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	Alendronate 70 mg weekly vs Raloxifine 60 mg daily Duration: 12 months
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Alendronate 10 mg daily vs Clodronate 100 mg weekly vs Risedronate 5 mg daily vs Raloxifine 60 mg daily Duration: 24 months
Ninkovic M et al., 2002[27] Pamidronate UK	Control vs Pamidronate 60 mg daily Duration: 1 day
Ravn P et al., 1996[28] Ibandronate Western Europe	Placebo daily vs Ibandronate 0.25 mg daily vs Ibandronate 0.5 mg daily vs Ibandronate 1.0 mg daily vs Ibandronate 25 mg daily vs Ibandronate 5.0 mg daily Duration: 12 months
Recker R et al., 2004[29] Ibandronate US, Western Europe	Placebo every 3 months vs Ibandronate 0.5 mg every 3 months vs Ibandronate 1 mg every 3 months Duration: 36 months
Reid IR et al., 1994[30] Pamidronate Australia/NZ	Pamidronate 150 mg daily vs Placebo daily Duration: 24 months
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	Zoledronic acid 0.25 mg every 3 months vs Zoledronic acid 0.5 mg every 3 months vs Zoledronic acid 1 mg every 3 months vs Zoledronic acid 2 mg every 6 months vs Zoledronic acid 4 mg yearly vs Placebo every 3 months Duration: 12 months
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	Placebo vs Raloxifine 60 mg daily vs Raloxifine 150 mg daily vs Estrogen 0.625 mg daily Duration: 36 months
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	Placebo and Alendronate 70 mg weekly vs Placebo and Risedronate 35 mg weekly Duration: 12 months
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	Control vs Estrogen 0.625 mg and Norgestrel 150 ug daily vs Etidronate 400 mg daily for 14 days every 3 months vs Estrogen .625 mg daily, Etidronate 400 mg daily for 14 days every 3 months and Norgestrel 150 ug daily Duration: 48 months

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 5-7: Interventions given to everyone, Run-in/Wash-out, Allowed other meds

Author, Year, Drug, Country, Trial name	Interventions given to everyone	Run-in period Wash-out period	Allowed other medications/interventions
Aris RM et al., 2000[1] Pamidronate US	Calcium, Vitamin D, Steroids	Run-in: None Wash-out: None	
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	Calcium, Vitamin D	Run-in: 2 mo of Placebo, 2 mo of Control Wash-out: None	
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	Calcium	Run-in: None Wash-out: None	
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Calcium, Vitamin D	Run-in: None Wash-out: None	
Coco M et al., 2003[5] Pamidronate US	Calcium, Vitamin D	Run-in: None Wash-out: None	
Cosman F et al., 2001[6] Estrogen, PTH US	Estrogen, Vitamin D	Run-in: None Wash-out: 12 mo of 301	
Cosman F et al., 2005[7] Alendronate, PTH US		Run-in: None Wash-out: None	
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	Calcium	Run-in: None Wash-out: None	
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	Calcium, Steroids, Azathioprine, Cyclosporine	Run-in: None Wash-out: None	
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	Calcium, Vitamin D	Run-in: 3 mo of Placebo for Subjects that completed run-in randomized, 3 mo of Estrogen for Subjects that completed run-in randomized, 3 mo of Calcium for Subjects that completed run-in randomized Wash-out: None	Medroxyprogesterone (if necessary)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 5-7: Interventions given to everyone, Run-in/Wash-out, Allowed other meds

Author, Year, Drug, Country, Trial name	Interventions given to everyone	Run-in period Wash-out period	Allowed other medications/interventions
Grotz W et al., 2001[11] Ibandronate Germany	Calcium, Estrogen, Vitamin D, Steroids	Run-in: None Wash-out: None	
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Calcium, Vitamin D, Ursodeoxycholic Acid	Run-in: None Wash-out: None	
Harris ST et al., 2001[13] Estrogen, Resindronate US	Calcium, Vitamin D, Medroxyprogesterone (if necessary)	Run-in: None Wash-out: None	
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	Calcium	Run-in: None Wash-out: None	
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark		Run-in: None Wash-out: None	
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	Calcium, Vitamin D	Run-in: None Wash-out: None	
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY		Run-in: None Wash-out: None	Medroxyprogesterone
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan		Run-in: None Wash-out: None	
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan		Run-in: None Wash-out: None	
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	Calcium, Estrogen, Testosterone, Vitamin D	Run-in: None Wash-out: None	
Kim SH et al., 2004[21] Pamidronate Asia	Steroids	Run-in: None Wash-out: None	
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	Calcium	Run-in: None Wash-out: None	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 5-7: Interventions given to everyone, Run-in/Wash-out, Allowed other meds

Author, Year, Drug, Country, Trial name	Interventions given to everyone	Run-in period Wash-out period	Allowed other medications/interventions
Lindsay R et al., 1997[23] Estrogen, PTH US	Calcium, Estrogen	Run-in: 1 yr of Estrogen Wash-out: None	
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Calcium, Estrogen, Vitamin D	Run-in: 2 wk of Placebo for Compliance Wash-out: None	
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	Calcium, Vitamin D	Run-in: None Wash-out: None	
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Calcium, Vitamin D	Run-in: None Wash-out: None	
Ninkovic M et al., 2002[27] Pamidronate UK	Steroids	Run-in: None Wash-out: None	
Ravn P et al., 1996[28] Ibandronate Western Europe	Calcium	Run-in: None Wash-out: None	
Recker R et al., 2004[29] Ibandronate US, Western Europe	Calcium, Vitamin D	Run-in: None Wash-out: None	
Reid IR et al., 1994[30] Pamidronate Australia/NZ	Calcium	Run-in: None Wash-out: None	
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	Calcium	Run-in: None Wash-out: None	
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	Calcium	Run-in: None Wash-out: None	
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	Calcium, Vitamin D	Run-in: None Wash-out: None	
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	Calcium, Vitamin D	Run-in: None Wash-out: None	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 8-9: Outcome assessment, demographics

Author, Year, Drug, Country, Trial name	Method of outcome assessment Timing of assessment	Age (average/range) Gender Ethnicity
Aris RM et al., 2000[1] Pamidronate US	Assessed at baseline, 6 mo, 12 mo, 18 mo, 24 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac.	28/18-38 50% male Not Reported
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	Assessed at baseline, 1 mo, 3 mo, 16 mo, 12 mo, 14 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Radial frac.	66/NR 0% male Caucasian, Hispanic, NOS
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	Assessed at baseline, 3 mo, 6 mo, 12 mo, 18 mo, 24 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Total fractures	62/42-82 0% male Caucasian, NOS
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Assessed at baseline, 6 mo, 12 mo, 18 mo, 24 mo, 30 mo, 36 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac., Total fractures, Symptomatic Vertebral Fractures, Radiographic Vertebral Fractures, Symptomatic Vertebral Fractures, Radiographic Vertebral Fractures	69/55-80 0% male Not Reported
Coco M et al., 2003[5] Pamidronate US	Assessed at baseline, 1 mo, 2 mo, 3 mo, 4 mo, 5 mo, 6 mo, 7 mo, 8 mo, 9 mo, 10 mo, 11 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Hip frac., Vertebral frac.	44/NR 50% male Caucasian, African-American, Hispanic, Asian
Cosman F et al., 2001[6] Estrogen, PTH US	Assessed at baseline, 6 mo, 12 mo, 18 mo, 24 mo, 30 mo, 36 mo, 48 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac., Total fractures	60/NR 0% male Not Reported
Cosman F et al., 2005[7] Alendronate, PTH US	Assessed at baseline, 3 mo, 6 mo, 9 mo, 12 mo, 15 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Hip frac., Radial frac., Vertebral frac., Total fractures, Radiographic Vertebral Fractures	68/NR 0% male Not Reported

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 8-9: Outcome assessment, demographics

Author, Year, Drug, Country, Trial name	Method of outcome assessment Timing of assessment	Age (average/range) Gender Ethnicity
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	Assessed at baseline, 12 wk, 24 wk, 36 wk, 48 wk: BMD - DEXA-Spine, Vertebral frac., Total fractures, Radiographic Vertebral Fractures	63/40-75 1% male Asian
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	Assessed at baseline, 6 mo, 12 mo, 18 mo: BMD - DEXA-Spine, Vertebral frac., Radiographic Vertebral Fractures	53/NR 95% male Not Reported
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	Assessed at baseline, 0 mo, 6 mo, 12 mo, 18 mo, 24 mo, 30 mo, 36 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Total fractures	72/65-90 0% male Not Reported
Grotz W et al., 2001[11] Ibandronate Germany	Assessed at baseline, 6 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac., Total fractures, Radiographic Vertebral Fractures, Symptomatic Vertebral Fractures	43/20-60 67% male Not Reported
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Assessed at baseline, 6 mo, 12 mo, 18 mo, 24 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac., Total fractures, Radiographic Vertebral Fractures	59/41-77 0% male Not Reported
Harris ST et al., 2001[13] Estrogen, Resindronate US	Assessed at baseline, 6 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Proximal humerus frac., Radial frac., Vertebral frac., Radiographic Vertebral Fractures	59/NR 0% male Not Reported
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	Assessed at baseline, 28 dy, 90 dy, 118 dy, 6 mo, 12 mo, 18 mo, 24 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Hip frac., Vertebral frac., Radiographic Vertebral Fractures	67/NR 0% male Caucasian

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 8-9: Outcome assessment, demographics

Author, Year, Drug, Country, Trial name	Method of outcome assessment Timing of assessment	Age (average/range) Gender Ethnicity
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	Assessed at baseline, 1 yr, 2 yr: BMD - DEXA-Hip, BMD - DEXA-Spine, Total fractures	53/45-59 0% male Caucasian, African-American, Asian, NOS
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	Assessed at baseline, 1 mo, 3 mo, 6 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Total fractures, Symptomatic Vertebral Fractures	69/NR 0% male Caucasian, NOS
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	Assessed at baseline, 3 mo, 6 mo, 9 mo, 12 mo, 15 mo, 18 mo, 21 mo, 24 mo: Hip frac., Radial frac., Vertebral frac.	NR/50-75 0% male Not Reported
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	Assessed at baseline, 3 mo, 6 mo: Vertebral frac., Radiographic Vertebral Fractures	74/63-84 0% male Not Reported
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	Assessed at baseline, 6 mo, 12 mo, 18 mo: BMD - DEXA-Spine, Hip frac., Proximal humerus frac., Radial frac., Vertebral frac., Radiographic Vertebral Fractures	71/60-83 0% male Not Reported
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	Assessed at baseline, 1 mo, 3 mo, 6 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac., Radiographic Vertebral Fractures	43/NR 50% male Not Reported
Kim SH et al., 2004[21] Pamidronate Asia	Assessed at baseline, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac., Total fractures	49/NR 51% male Not Reported

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 8-9: Outcome assessment, demographics

Author, Year, Drug, Country, Trial name	Method of outcome assessment Timing of assessment	Age (average/range) Gender Ethnicity
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	Assessed at baseline, 24 wk, 48 wk, 72 wk, 96 wk: Vertebral frac.	72/NR 4% male Not Reported
Lindsay R et al., 1997[23] Estrogen, PTH US	Assessed at baseline, 1 mo, 3 mo, 6 mo, 12 mo, 18 mo, 24 mo, 30 mo, 36 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac.	62/NR 0% male Not Reported
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Assessed at 6 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Hip frac., Radial frac., Vertebral frac., Total fractures, Symptomatic Vertebral Fractures	62/NR 0% male Caucasian, NOS
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	Assessed at baseline, 6 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Hip frac., Proximal humerus frac., Radial frac., Vertebral frac., Total fractures	64/NR 0% male Caucasian, African-American, Asian, NOS
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Assessed at 12 mo, 24 mo: BMD - DEXA-Spine, Hip frac., Radial frac., Vertebral frac., Symptomatic Vertebral Fractures	68/NR 0% male Not Reported
Ninkovic M et al., 2002[27] Pamidronate UK	Assessed at baseline, 3 mo, 6 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Proximal humerus frac., Vertebral frac., Total fractures, Radiographic Vertebral Fractures, Symptomatic Vertebral Fractures	51/19-68 50% male Not Reported
Ravn P et al., 1996[28] Ibandronate Western Europe	Assessed at baseline, 3 mo, 6 mo, 9 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Total fractures	65/NR 0% male Caucasian

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 8-9: Outcome assessment, demographics

Author, Year, Drug, Country, Trial name	Method of outcome assessment Timing of assessment	Age (average/range) Gender Ethnicity
Recker R et al., 2004[29] Ibandronate US, Western Europe	Assessed at baseline, 6 mo, 12 mo, 18 mo, 24 mo, 30 mo, 36 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Hip frac., Vertebral frac., Total fractures, Radiographic Vertebral Fractures	67/55-76 0% male Not Reported
Reid IR et al., 1994[30] Pamidronate Australia/NZ	Assessed at baseline, 1 yr, 2 yr: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac., Radiographic Vertebral Fractures	66/NR 0% male Not Reported
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	Assessed at baseline, 3 mo, 6 mo, 9 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac.	64/45-80 0% male Caucasian, NOS
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	Assessed at baseline, 3 mo, 6 mo, 9 mo, 12 mo, 15 mo, 18 mo, 21 mo, 24 mo, 30 mo, 36 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac., Radiographic Vertebral Fractures	53/NR 0% male Caucasian, NOS
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	Assessed at baseline, 3 mo, 6 mo, 12 mo: BMD - DEXA-Hip, BMD - DEXA-Spine, Total fractures	65/NR 0% male Caucasian, African-American, Asian, NOS
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	Assessed at baseline, 2 yr, 4 yr: BMD - DEXA-Hip, BMD - DEXA-Spine, Vertebral frac.	65/58-72 0% male Caucasian

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 10-12: Screened etc., Withdrawn, Results

Author, Year, Drug, Country, Trial name	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results - 1
Aris RM et al., 2000[1] Pamidronate US	44/37/37	3/0/34	Number of people with fracture: long bone fracture at 24 months: Pamidronate vs Control 18.8% vs 33.3% OR = 0.48 (95% CI 0.11, 2.17)
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	265/149/149	37/1/143	Number of people with fracture: nonvertebral at 14 months: Alendronate vs PTH 13.7% vs 4.1% OR = 3.24 (95% CI 1.04, 10.07)
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	NR/NR/425	105/17/395	Number of people with fracture: any clinical fracture adverse effect (mostly nonvertebral) at 24 months: Alendronate vs Estrogen 5.0% vs 7.0% OR = 0.77 (95% CI 0.26, 2.25) Alendronate vs Placebo 5.0% vs 8.0% OR = 0.65 (95% CI 0.16, 2.66) Alendronate+Estrogen vs Alendronate 6.0% vs 5.0% OR = 1.05 (95% CI 0.34, 3.30) Alendronate+Estrogen vs Estrogen 6.0% vs 7.0% OR = 0.81 (95% CI 0.31, 2.09) Alendronate+Estrogen vs Placebo 6.0% vs 8.0% OR = 0.68 (95% CI 0.18, 2.56) Estrogen vs Placebo 7.0% vs 8.0% OR = 0.86 (95% CI 0.25, 2.97)
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	18447/NR/2946	NR/NR/2929	Number of people with fracture: clinical osteoporotic nonvertebral at 36 months: Ibandronate daily vs Ibandronate intermittent 9.1% vs 8.9% OR = 1.03 (95% CI 0.75, 1.40) Ibandronate daily vs Placebo 9.1% vs 8.2% OR = 1.00 (95% CI 0.73, 1.36) Ibandronate intermittent vs Placebo 8.9% vs 8.2% OR = 1.09 (95% CI 0.80, 1.50)
Coco M et al., 2003[5] Pamidronate US	112/98/72	13/NR/59	Number of people with fracture: hip fractures at 12 months: Pamidronate vs Control 0.0% vs 0.0% OR = NC
Cosman F et al., 2001[6] Estrogen, PTH US	280/174/52	6/5/41	Number of people with fracture: nonvertebral (toe) at 36 months: PTH+Estrogen vs Estrogen 0.0% vs 4.0% OR = 0.12 (95% CI 0.00, 6.31)
Cosman F et al., 2005[7] Alendronate, PTH US	1345/131/126	18/0/108	Number of people with fracture: clinical nonspinal fracture at 15 months: Alendronate+PTH cyclic vs Alendronate 5.9% vs 5.6% OR = 1.06 (95% CI 0.14, 7.88) Alendronate+PTH cyclic vs Alendronate+PTH daily 5.9% vs 10.5% OR = 0.55 (95% CI 0.10, 2.89) Alendronate+PTH daily vs Alendronate 10.5% vs 5.6% OR = 1.93 (95% CI 0.37, 10.14)
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	362/NR/235	32/3/209	Number of people with fracture: nonvertebral at 11.2 months: Etindronate vs Risedronate 3.4% vs 5.9% OR = 0.57 (95% CI 0.17, 1.91)
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	NR/NR/40	NR/NR/40	Number of people with fracture: vertebral at 18 months: Calcitonin vs Calcidiol 30.8% vs 0.0% OR = 9.71 (95% CI 1.20, 78.42) Etindronate vs Calcidiol 21.4% vs 0.0% OR = 8.08 (95% CI 0.76, 85.33) Etindronate vs Calcitonin 21.4% vs 30.8% OR = 0.63 (95% CI 0.12, 3.39)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 10-12: Screened etc., Withdrawn, Results

Author, Year, Drug, Country, Trial name	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results - 1
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	573/548/373	26/8/373	Number of people with fracture: clinical fracture at 36 months: Alendronate vs Estrogen 8.0% vs 5.0% OR = 1.43 (95% CI 0.44, 4.58) Alendronate vs Placebo 8.0% vs 10.0% OR = 0.76 (95% CI 0.27, 2.12) Alendronate+Estrogen vs Alendronate 4.0% vs 8.0% OR = 0.56 (95% CI 0.16, 1.87) Alendronate+Estrogen vs Estrogen 4.0% vs 5.0% OR = 0.78 (95% CI 0.21, 2.98) Alendronate+Estrogen vs Placebo 4.0% vs 10.0% OR = 0.43 (95% CI 0.14, 1.34) Estrogen vs Placebo 5.0% vs 10.0% OR = 0.54 (95% CI 0.18, 1.60)
Grotz W et al., 2001[11] Ibandronate Germany	114/98/80	8/0/72	Number of people with fracture: arm at 12 months: Ibandronate vs Control 2.5% vs 2.5% OR = 1.00 (95% CI 0.06, 16.27)
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	NR/NR/32	6/0/26	Number of people with fracture: nonvertebral at 24 months: Alendronate vs Etindronate 15.4% vs 7.7% OR = 2.06 (95% CI 0.19, 21.85)
Harris ST et al., 2001[13] Estrogen, Resindronate US	NR/NR/524	76/NR/524	Number of people with fracture: nonvertebral at 12 months: Risendronate+Estrogen vs Estrogen 0.8% vs 2.7% OR = 0.29 (95% CI 0.08, 1.11)
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	NR/NR/39	9/0/30	Number of people with fracture: hip orother appendicular fracture at 24 months: PTH+Calcitonin vs PTH 0.0% vs 0.0% OR = NC
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	NR/NR/1609	139/26/1460	Number of people with fracture: traumatic nonvertebral at 24 months: Alendronate 2.5mg vs Alendronate 5mg 4.0% vs 4.0% OR = 0.98 (95% CI 0.54, 1.80) Alendronate 2.5mg vs Estrogen+Progestin 4.0% vs 3.0% OR = 1.56 (95% CI 0.56, 4.39) Alendronate 2.5mg vs Placebo 4.0% vs 3.0% OR = 1.62 (95% CI 0.83, 3.16) Alendronate 5mg vs Estrogen+Progestin 4.0% vs 3.0% OR = 1.58 (95% CI 0.56, 4.43) Alendronate 5mg vs Placebo 4.0% vs 3.0% OR = 1.65 (95% CI 0.85, 3.21) Estrogen+Progestin vs Placebo 3.0% vs 3.0% OR = 0.97 (95% CI 0.28, 3.39)
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	1036/NR/549	107/3/NR	Number of people with fracture: clinically diagnosed vertebral or nonvertebral at 12 months: Alendronate vs Placebo 2.7% vs 1.9% OR = 1.52 (95% CI 0.34, 6.67) Alendronate vs Risedronate 2.7% vs 2.7% OR = 1.04 (95% CI 0.33, 3.27) Risedronate vs Placebo 2.7% vs 1.9% OR = 1.47 (95% CI 0.33, 6.52)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 10-12: Screened etc., Withdrawn, Results

Author, Year, Drug, Country, Trial name	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results - 1
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	739/NR/396	24/11/NR	Number of people with fracture: vertebral at 24 months: Alfacalcidol vs Control (no treatment) 16.7% vs 25.8% OR = 0.58 (95% CI 0.25, 1.34) Alfacalcidol vs VitK 16.7% vs 13.6% OR = 1.26 (95% CI 0.49, 3.26) Calcitonin vs Alfacalcidol 12.1% vs 16.7% OR = 0.69 (95% CI 0.26, 1.83) Calcitonin vs Control (no treatment) 12.1% vs 25.8% OR = 0.41 (95% CI 0.17, 0.99) - NNT=7.3 (95% CI 3.7-212.8) Calcitonin vs Estrogen+Medroxyprogesterone 12.1% vs 10.6% OR = 1.16 (95% CI 0.40, 3.39) Calcitonin vs VitK 12.1% vs 13.6% OR = 0.87 (95% CI 0.32, 2.41) Control (no treatment) vs VitK 25.8% vs 13.6% OR = 2.14 (95% CI 0.91, 5.03) Estrogen+Medroxyprogesterone vs Alfacalcidol 10.6% vs 16.7% OR = 0.60 (95% CI 0.22, 1.62) Estrogen+Medroxyprogesterone vs Control (no treatment) 10.6% vs 25.8% OR = 0.36 (95% CI 0.15, 0.88) - NNT=6.6 (95% CI 3.6-44.6) Estrogen+Medroxyprogesterone vs VitK 10.6% vs 13.6% OR = 0.75 (95% CI 0.27, 2.14) Etindronate vs Alfacalcidol 12.1% vs 16.7% OR = 0.69 (95% CI 0.26, 1.83) Etindronate vs Calcitonin 12.1% vs 12.1% OR = 1.00 (95% CI 0.35, 2.83) Etindronate vs Control (no treatment) 12.1% vs 25.8% OR = 0.41 (95% CI 0.17, 0.99) - NNT=7.4 (95% CI 3.7-212.8) Etindronate vs Estrogen+Medroxyprogesterone 12.1% vs 10.6% OR = 1.16 (95% CI 0.40, 3.39) Etindronate vs VitK 12.1% vs 13.6% OR = 0.87 (95% CI 0.32, 2.41)
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	NR/NR/50	0/0/50	Number of people with fracture: vertebral at 6 months: Alendronate vs Etindronate 0.0% vs 4.0% OR = 0.14 (95% CI 0.00, 6.82)
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	NR/NR/40	NR/NR/NR	Number of people with fracture: nonvertebral at 18 months: Alendronate+Etindronate vs Etindronate 0.0% vs 0.0% OR = NC
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	115/108/99	33/0/72	Number of people with fracture: vertebral at 12 months: Pamidronate vs Control 8.6% vs 13.2% OR = 0.57 (95% CI 0.13, 2.48)
Kim SH et al., 2004[21] Pamidronate Asia	NR/NR/50	0/5/45	Number of people with fracture: vertebral at 12 months: Pamidronate vs Control 4.0% vs 30.0% OR = 0.14 (95% CI 0.03, 0.72) - NNT=3.8 (95% CI 2.1-22.3)
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	NR/NR/547	157/17/433	Number of people with fracture: vertebral (new or worsening) at 24 weeks: Etindronate vs Risedronate 6.0% vs 8.8% OR = 0.66 (95% CI 0.32, 1.36)
Lindsay R et al., 1997[23] Estrogen, PTH US	NR/NR/40	6/4/34	Number of people with fracture: vertebral (15% decrease in vertebral height) at 36 months: PTH+Estrogen vs Estrogen 15.4% vs 41.2% OR = 0.31 (95% CI 0.06, 1.44)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 10-12: Screened etc., Withdrawn, Results

Author, Year, Drug, Country, Trial name	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results - 1
Lindsay R et al., 1999[24] Alendronate, Estrogen US	1855/565/428	32/2/428	Number of people with fracture: ankle at 12 months: Alendronate+Estrogen vs Estrogen 0.5% vs 0.5% OR = 0.94 (95% CI 0.06, 15.11)
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	1200/508/456	76/8/405	Number of people with fracture: all clinical fractures at 12 months: Alendronate vs Raloxifine 2.3% vs 3.5% OR = 0.65 (95% CI 0.22, 1.95)
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	NR/NR/2000	NR/NR/NR	Number of people with fracture: femoral at 12 months: Alendronate vs Clodronate 0.1% vs 0.0% OR = 6.05 (95% CI 0.12, 312.4) Alendronate vs Raloxifine 0.1% vs 0.0% OR = 3.00 (95% CI 0.00, 2746) Alendronate vs Risedronate 0.1% vs 0.0% OR = 3.00 (95% CI 0.00, 2746) Raloxifine vs Clodronate 0.0% vs 0.0% OR = NC Risedronate vs Clodronate 0.0% vs 0.0% OR = NC Risedronate vs Raloxifine 0.0% vs 0.0% OR = NC
Ninkovic M et al., 2002[27] Pamidronate UK	NR/NR/99	28/0/NR	Number of people with fracture: nonvertebral at 12 months: Pamidronate vs Placebo 2.9% vs 2.4% OR = 1.21 (95% CI 0.07, 19.96)
Ravn P et al., 1996[28] Ibandronate Western Europe	NR/821/180	39/2/180	Number of people with fracture: fracture at 12 months: Ibandronate 0.25 vs Ibandronate 0.5 0.0% vs 0.0% OR = NC Ibandronate 0.25 vs Ibandronate 1 0.0% vs 0.0% OR = NC Ibandronate 0.25 vs Ibandronate 2.5 0.0% vs 0.0% OR = NC Ibandronate 0.25 vs Ibandronate 5 0.0% vs 0.0% OR = NC Ibandronate 0.25 vs Placebo 0.0% vs 3.3% OR = 0.14 (95% CI 0.00, 6.82) Ibandronate 0.5 vs Ibandronate 1 0.0% vs 0.0% OR = NC Ibandronate 0.5 vs Ibandronate 2.5 0.0% vs 0.0% OR = NC Ibandronate 0.5 vs Ibandronate 5 0.0% vs 0.0% OR = NC Ibandronate 0.5 vs Placebo 0.0% vs 3.3% OR = 0.14 (95% CI 0.00, 6.82) Ibandronate 1 vs Ibandronate 2.5 0.0% vs 0.0% OR = NC Ibandronate 1 vs Ibandronate 5 0.0% vs 0.0% OR = NC Ibandronate 1 vs Placebo 0.0% vs 3.3% OR = 0.14 (95% CI 0.00, 6.82) Ibandronate 2.5 vs Ibandronate 5 0.0% vs 0.0% OR = NC Ibandronate 2.5 vs Placebo 0.0% vs 3.3% OR = 0.14 (95% CI 0.00, 6.82) Ibandronate 5 vs Placebo 0.0% vs 3.3% OR = 0.14 (95% CI 0.00, 6.82)
Recker R et al., 2004[29] Ibandronate US, Western Europe	16632/NR/2862	503/29/2860	Number of people with fracture: morphometric vertebral fractures at 36 months: Ibandronate 0.5 vs Ibandronate 1 8.7% vs 9.2% OR = 0.96 (95% CI 0.69, 1.33) Ibandronate 0.5 vs Placebo 8.7% vs 10.7% OR = 0.78 (95% CI 0.57, 1.07) Ibandronate 1 vs Placebo 9.2% vs 10.7% OR = 0.82 (95% CI 0.60, 1.11)
Reid IR et al., 1994[30] Pamidronate Australia/NZ	NR/NR/61	13/0/48	Number of people with fracture: vertebral at 24 months: Pamidronate vs Placebo 26.9% vs 45.5% OR = 0.45 (95% CI 0.14, 1.46)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 10-12: Screened etc., Withdrawn, Results

Author, Year, Drug, Country, Trial name	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results - 1
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	NR/NR/351	35/NR/351	Number of people with fracture: nonvertebral at 12 months: Zoledronic acid 1x4 vs Placebo 1.7% vs 1.7% OR = 0.98 (95% CI 0.06, 15.91) Zoledronic acid 1x4 vs Zoledronic acid 2x2 1.7% vs 1.6% OR = 1.02 (95% CI 0.06, 16.45) Zoledronic acid 1x4 vs Zoledronic acid 4x0.25 1.7% vs 0.0% OR = 7.39 (95% CI 0.15, 372.4) Zoledronic acid 1x4 vs Zoledronic acid 4x0.5 1.7% vs 1.7% OR = 0.97 (95% CI 0.06, 15.64) Zoledronic acid 1x4 vs Zoledronic acid 4x1 1.7% vs 3.8% OR = 0.45 (95% CI 0.05, 4.39) Zoledronic acid 2x2 vs Placebo 1.6% vs 1.7% OR = 0.97 (95% CI 0.06, 15.65) Zoledronic acid 2x2 vs Zoledronic acid 4x0.25 1.6% vs 0.0% OR = 7.27 (95% CI 0.14, 366.4) Zoledronic acid 2x2 vs Zoledronic acid 4x0.5 1.6% vs 1.7% OR = 0.95 (95% CI 0.06, 15.39) Zoledronic acid 2x2 vs Zoledronic acid 4x1 1.6% vs 3.8% OR = 0.44 (95% CI 0.04, 4.32) Zoledronic acid 4x0.25 vs Placebo 0.0% vs 1.7% OR = 0.13 (95% CI 0.00, 6.71) Zoledronic acid 4x0.25 vs Zoledronic acid 4x0.5 0.0% vs 1.7% OR = 0.13 (95% CI 0.00, 6.59) Zoledronic acid 4x0.25 vs Zoledronic acid 4x1 0.0% vs 3.8% OR = 0.12 (95% CI 0.01, 1.89) Zoledronic acid 4x0.5 vs Placebo 1.7% vs 1.7% OR = 1.02 (95% CI 0.06, 16.46) Zoledronic acid 4x0.5 vs Zoledronic acid 4x1 1.7% vs 3.8% OR = 0.46 (95% CI 0.05, 4.54) Zoledronic acid 4x1 vs Placebo 3.8% vs 1.7% OR = 2.20 (95% CI 0.22, 21.70)
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	NR/1522/619	234/28/619	Number of people with fracture: vertebral fracture at 36 months: Estrogen vs Placebo 1.0% vs 1.1% OR = 0.88 (95% CI 0.05, 14.27) Raloxifine 150mg vs Estrogen 1.0% vs 1.0% OR = 1.00 (95% CI 0.06, 16.10) Raloxifine 150mg vs Placebo 1.0% vs 1.1% OR = 0.88 (95% CI 0.05, 14.27) Raloxifine 60mg vs Estrogen 3.3% vs 1.0% OR = 3.11 (95% CI 0.43, 22.51) Raloxifine 60mg vs Placebo 3.3% vs 1.1% OR = 2.73 (95% CI 0.38, 19.73) Raloxifine 60mg vs Raloxifine 150mg 3.3% vs 1.0% OR = 3.11 (95% CI 0.43, 22.51)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 10-12: Screened etc., Withdrawn, Results

Author, Year, Drug, Country, Trial name	Screened/Eligible/Enrolled	Withdrawn/Lost to FU/Analyzed	Results - 1
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	1759/NR/1053	138/23/945	Number of people with fracture: fracture at 12 months: Alendronate vs Risedronate 5.0% vs 3.8% OR = 1.35 (95% CI 0.75, 2.43)
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	350/NR/72	13/1/58	Number of people with fracture: nonvertebral at 48 months: Estrogen+Progesterone vs Control 6.7% vs 7.1% OR = 0.93 (95% CI 0.06, 15.69) Etindonate+Estrogen+Progesterone vs Estrogen+Progesterone 6.7% vs 6.7% OR = 1.00 (95% CI 0.06, 16.79) Etindronate vs Control 7.1% vs 7.1% OR = 1.00 (95% CI 0.06, 16.85) Etindronate vs Estrogen+Progesterone 7.1% vs 6.7% OR = 1.07 (95% CI 0.06, 18.10) Etindronate+Estrogen+Progesterone vs Control 6.7% vs 7.1% OR = 0.93 (95% CI 0.06, 15.69) Etindronate+Estrogen+Progesterone vs Etindronate 6.7% vs 7.1% OR = 0.93 (95% CI 0.06, 15.69)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 2
Aris RM et al., 2000[1] Pamidronate US	Number of people with fracture: vertebral at 24 months: Pamidronate vs Control 18.8% vs 5.6% OR = 3.43 (95% CI 0.44, 26.92)
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Number of people with fracture: clinical vertebral at 36 months: Ibandronate daily vs Ibandronate intermittent 2.3% vs 2.3% OR = 1.00 (95% CI 0.55, 1.82) Ibandronate daily vs Placebo 2.3% vs 4.2% OR = 0.54 (95% CI 0.32, 0.88) - NNT=51.3 (95% CI 28.5-258.4) Ibandronate intermittent vs Placebo 2.3% vs 4.2% OR = 0.54 (95% CI 0.32, 0.88) - NNT=51.3 (95% CI 28.5-258.4) Number of people with fracture: vertebral at 36 months: Ibandronate daily vs Ibandronate intermittent 3.8% vs 4.0% OR = 0.95 (95% CI 0.60, 1.50) Ibandronate daily vs Placebo 3.8% vs 7.5% OR = 0.50 (95% CI 0.34, 0.73) - NNT=27.0 (95% CI 17.5-60.2) Ibandronate intermittent vs Placebo 4.0% vs 7.5% OR = 0.52 (95% CI 0.36, 0.77) - NNT=28.7 (95% CI 18.2-69.9)
Coco M et al., 2003[5] Pamidronate US	Number of people with fracture: vertebral at 12 months: Pamidronate vs Control 3.2% vs 7.1% OR = 0.45 (95% CI 0.04, 4.52)
Cosman F et al., 2001[6] Estrogen, PTH US	Number of people with fracture: vertebral(15% decrease in vertebral height) at 36 months: PTH+Estrogen vs Estrogen 7.4% vs 48.0% OR = 0.13 (95% CI 0.04, 0.45) - NNT=2.5 (95% CI 1.6-5.4) Number of people with fracture: vertebral(20% decrease in vertebral height) at 36 months: PTH+Estrogen vs Estrogen 0.0% vs 28.0% OR = 0.09 (95% CI 0.02, 0.46) - NNT=3.6 (95% CI 2.2-9.6)
Cosman F et al., 2005[7] Alendronate, PTH US	Number of people with fracture: new or worsening vertebral at 15 months: Alendronate+PTH cyclic vs Alendronate 6.0% vs 11.0% OR = 0.52 (95% CI 0.10, 2.73) Alendronate+PTH cyclic vs Alendronate+PTH daily 6.0% vs 3.0% OR = 2.23 (95% CI 0.22, 22.24) Alendronate+PTH daily vs Alendronate 3.0% vs 11.0% OR = 0.27 (95% CI 0.04, 1.61)
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	Number of people with fracture: vertebral at 11.2 months: Etindronate vs Risedronate 1.8% vs 0.0% OR = 6.81 (95% CI 0.42, 110.0)
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 2
Grotz W et al., 2001[11] Ibandronate Germany	Number of people with fracture: vertebral at 12 months: Ibandronate vs Control 2.5% vs 2.5% OR = 1.00 (95% CI 0.06, 16.27)
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Number of people with fracture: vertebral at 24 months: Alendronate vs Etindronate 0.0% vs 0.0% OR = NC
Harris ST et al., 2001[13] Estrogen, Resindronate US	Number of people with fracture: vertebral at 12 months: Risendronate+Estrogen vs Estrogen 1.8% vs 2.6% OR = 0.69 (95% CI 0.15, 3.07)
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	Number of people with fracture: vertebral at 24 months: PTH+Calcitonin vs PTH 30.8% vs 9.1% OR = 3.52 (95% CI 0.51, 24.41)
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	Number of people with fracture: vertebral at 18 months: Alendronate+Etindronate vs Etindronate 0.0% vs 0.0% OR = NC
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	
Kim SH et al., 2004[21] Pamidronate Asia	
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 2
Lindsay R et al., 1997[23] Estrogen, PTH US	Number of people with fracture: vertebral (20% decrease in vertebral height) at 36 months: PTH+Estrogen vs Estrogen 7.7% vs 23.5% OR = 0.33 (95% CI 0.05, 2.23)
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Number of people with fracture: arm at 12 months: Alendronate+Estrogen vs Estrogen 0.0% vs 0.5% OR = 0.13 (95% CI 0.00, 6.42) Number of people with fracture: foot/toe at 12 months: Alendronate+Estrogen vs Estrogen 3.9% vs 2.1% OR = 1.87 (95% CI 0.59, 5.88)
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Number of people with fracture: radial at 12 months: Alendronate vs Clodronate 0.1% vs 0.0% OR = 6.05 (95% CI 0.12, 312.4) Alendronate vs Raloxifine 0.1% vs 0.0% OR = 3.00 (95% CI 0.00, 2746) Alendronate vs Risedronate 0.1% vs 0.0% OR = 3.00 (95% CI 0.00, 2746) Raloxifine vs Clodronate 0.0% vs 0.0% OR = NC Risedronate vs Clodronate 0.0% vs 0.0% OR = NC Risedronate vs Raloxifine 0.0% vs 0.0% OR = NC Number of people with fracture: total fractures at 12 months: Alendronate vs Risedronate 0.2% vs 0.0% OR = 3.01 (95% CI 0.02, 373.9)
Ninkovic M et al., 2002[27] Pamidronate UK	Number of people with fracture: vertebral at 12 months: Pamidronate vs Placebo 8.8% vs 2.4% OR = 3.48 (95% CI 0.47, 25.98)
Ravn P et al., 1996[28] Ibandronate Western Europe	
Recker R et al., 2004[29] Ibandronate US, Western Europe	
Reid IR et al., 1994[30] Pamidronate Australia/NZ	
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	Number of people with fracture: vertebral at 12 months: Zoledronic acid 1x4 vs Placebo 0.0% vs 0.0% OR = NC Zoledronic acid 1x4 vs Zoledronic acid 2x2 0.0% vs 0.0% OR = NC Zoledronic acid 1x4 vs Zoledronic acid 4x0.25 0.0% vs 0.0% OR = NC Zoledronic acid 1x4 vs Zoledronic acid 4x0.5 0.0% vs 0.0% OR = NC Zoledronic acid 1x4 vs Zoledronic acid 4x1 0.0% vs 0.0% OR = NC Zoledronic acid 2x2 vs Placebo 0.0% vs 0.0% OR = NC Zoledronic acid 2x2 vs Zoledronic acid 4x0.25 0.0% vs 0.0% OR = NC Zoledronic acid 2x2 vs Zoledronic acid 4x0.5 0.0% vs 0.0% OR = NC Zoledronic acid 2x2 vs Zoledronic acid 4x1 0.0% vs 0.0% OR = NC Zoledronic acid 4x0.25 vs Placebo 0.0% vs 0.0% OR = NC Zoledronic acid 4x0.25 vs Zoledronic acid 4x0.5 0.0% vs 0.0% OR = NC Zoledronic acid 4x0.25 vs Zoledronic acid 4x1 0.0% vs 0.0% OR = NC Zoledronic acid 4x0.5 vs Placebo 0.0% vs 0.0% OR = NC Zoledronic acid 4x0.5 vs Zoledronic acid 4x1 0.0% vs 0.0% OR = NC Zoledronic acid 4x1 vs Placebo 0.0% vs 0.0% OR = NC

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 2
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	Number of people with fracture: vertebral at 48 months: Estrogen+Progesterone vs Control 13.3% vs 35.7% OR = 0.31 (95% CI 0.06, 1.64) Etindonate+Estrogen+Progesterone vs Estrogen+Progesterone 6.7% vs 13.3% OR = 0.49 (95% CI 0.05, 5.10) Etindronate vs Control 21.4% vs 35.7% OR = 0.51 (95% CI 0.10, 2.55) Etindronate vs Estrogen+Progesterone 21.4% vs 13.3% OR = 1.73 (95% CI 0.26, 11.50) Etindronate+Estrogen+Progesterone vs Control 6.7% vs 35.7% OR = 0.18 (95% CI 0.03, 1.06) Etindronate+Estrogen+Progesterone vs Etindronate 6.7% vs 21.4% OR = 0.30 (95% CI 0.04, 2.40)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 3
Aris RM et al., 2000[1] Pamidronate US	
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	
Coco M et al., 2003[5] Pamidronate US	
Cosman F et al., 2001[6] Estrogen, PTH US	
Cosman F et al., 2005[7] Alendronate, PTH US	
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	
Grotz W et al., 2001[11] Ibandronate Germany	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 3
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	
Harris ST et al., 2001[13] Estrogen, Resindronate US	
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	
Kim SH et al., 2004[21] Pamidronate Asia	
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	
Lindsay R et al., 1997[23] Estrogen, PTH US	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 3
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Number of people with fracture: fracture (all kinds) at 12 months: Alendronate+Estrogen vs Estrogen 7.4% vs 4.7% OR = 1.59 (95% CI 0.70, 3.64) Number of people with fracture: hand at 12 months: Alendronate+Estrogen vs Estrogen 0.5% vs 0.0% OR = 6.96 (95% CI 0.14, 351.7)
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Number of people with fracture: vertebral at 12 months: Alendronate vs Clodronate 0.2% vs 0.4% OR = 0.53 (95% CI 0.09, 3.11) Alendronate vs Raloxifine 0.2% vs 0.0% OR = 3.01 (95% CI 0.02, 373.9) Alendronate vs Risedronate 0.2% vs 0.0% OR = 3.01 (95% CI 0.02, 373.9) Raloxifine vs Clodronate 0.0% vs 0.4% OR = 0.32 (95% CI 0.01, 11.91) Risedronate vs Clodronate 0.0% vs 0.4% OR = 0.32 (95% CI 0.01, 11.91) Risedronate vs Raloxifine 0.0% vs 0.0% OR = NC Number of people with fracture: femoral at 24 months: Alendronate vs Clodronate 0.2% vs 0.3% OR = 0.80 (95% CI 0.11, 5.75) Alendronate vs Raloxifine 0.2% vs 0.0% OR = 3.01 (95% CI 0.02, 373.9) Alendronate vs Risedronate 0.2% vs 0.0% OR = 3.01 (95% CI 0.02, 373.9) Raloxifine vs Clodronate 0.0% vs 0.3% OR = 0.32 (95% CI 0.00, 26.74) Risedronate vs Clodronate 0.0% vs 0.3% OR = 0.32 (95% CI 0.00, 26.74) Risedronate vs Raloxifine 0.0% vs 0.0% OR = NC
Ninkovic M et al., 2002[27] Pamidronate UK	
Ravn P et al., 1996[28] Ibandronate Western Europe	
Recker R et al., 2004[29] Ibandronate US, Western Europe	
Reid IR et al., 1994[30] Pamidronate Australia/NZ	
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 3
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 4
Aris RM et al., 2000[1] Pamidronate US	
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	
Coco M et al., 2003[5] Pamidronate US	
Cosman F et al., 2001[6] Estrogen, PTH US	
Cosman F et al., 2005[7] Alendronate, PTH US	
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	
Grotz W et al., 2001[11] Ibandronate Germany	
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 4
Harris ST et al., 2001[13] Estrogen, Resindronate US	
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	
Kim SH et al., 2004[21] Pamidronate Asia	
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	
Lindsay R et al., 1997[23] Estrogen, PTH US	
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Number of people with fracture: hip at 12 months: Alendronate+Estrogen vs Estrogen 0.0% vs 0.0% OR = NC Number of people with fracture: patella at 12 months: Alendronate+Estrogen vs Estrogen 0.5% vs 0.0% OR = 6.96 (95% CI 0.14, 351.7)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 4
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Number of people with fracture: radial at 24 months: Alendronate vs Clodronate 0.0% vs 0.0% OR = NC Alendronate vs Raloxifine 0.0% vs 0.0% OR = NC Alendronate vs Risedronate 0.0% vs 0.0% OR = NC Raloxifine vs Clodronate 0.0% vs 0.0% OR = NC Risedronate vs Clodronate 0.0% vs 0.0% OR = NC Risedronate vs Raloxifine 0.0% vs 0.0% OR = NC Number of people with fracture: vertebral at 24 months: Alendronate vs Clodronate 0.4% vs 0.4% OR = 1.07 (95% CI 0.24, 4.75) Alendronate vs Raloxifine 0.4% vs 0.0% OR = 3.01 (95% CI 0.10, 91.52) Alendronate vs Risedronate 0.4% vs 0.0% OR = 3.01 (95% CI 0.10, 91.52) Raloxifine vs Clodronate 0.0% vs 0.4% OR = 0.32 (95% CI 0.01, 11.91) Risedronate vs Clodronate 0.0% vs 0.4% OR = 0.32 (95% CI 0.01, 11.91) Risedronate vs Raloxifine 0.0% vs 0.0% OR = NC
Ninkovic M et al., 2002[27] Pamidronate UK	
Ravn P et al., 1996[28] Ibandronate Western Europe	
Recker R et al., 2004[29] Ibandronate US, Western Europe	
Reid IR et al., 1994[30] Pamidronate Australia/NZ	
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 5
Aris RM et al., 2000[1] Pamidronate US	
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	
Coco M et al., 2003[5] Pamidronate US	
Cosman F et al., 2001[6] Estrogen, PTH US	
Cosman F et al., 2005[7] Alendronate, PTH US	
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	
Grotz W et al., 2001[11] Ibandronate Germany	
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 5
Harris ST et al., 2001[13] Estrogen, Resindronate US	
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	
Kim SH et al., 2004[21] Pamidronate Asia	
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	
Lindsay R et al., 1997[23] Estrogen, PTH US	
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Number of people with fracture: rib at 12 months: Alendronate+Estrogen vs Estrogen 1.5% vs 0.5% OR = 2.58 (95% CI 0.36, 18.46) Number of people with fracture: symptomatic vertebral fracture at 12 months: Alendronate+Estrogen vs Estrogen 0.0% vs 0.0% OR = NC

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 12: Results continued

Author, Year, Drug, Country, Trial name	Results - 5
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	
Ninkovic M et al., 2002[27] Pamidronate UK	
Ravn P et al., 1996[28] Ibandronate Western Europe	
Recker R et al., 2004[29] Ibandronate US, Western Europe	
Reid IR et al., 1994[30] Pamidronate Australia/NZ	
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 12-13: Results continued, Methods of AE assessment

Author, Year, Drug, Country, Trial name	Results - 6	Methods of adverse events assessment
Aris RM et al., 2000[1] Pamidronate US		Monitored, elicited by investigator
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel		Monitored, elicited by investigator
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP		Bone histology
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE		Monitored
Coco M et al., 2003[5] Pamidronate US		NR
Cosman F et al., 2001[6] Estrogen, PTH US		NR
Cosman F et al., 2005[7] Alendronate, PTH US		Monitored
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH		Monitored, reported by patient
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe		NR
Greenspan SL et al., 2003[10] Alendronate, Estrogen US		NR
Grotz W et al., 2001[11] Ibandronate Germany		Monitored, reported by patient
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe		NR

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 12-13: Results continued, Methods of AE assessment

Author, Year, Drug, Country, Trial name	Results - 6	Methods of adverse events assessment
Harris ST et al., 2001[13] Estrogen, Resindronate US		Monitored, elicited by investigator
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada		NR
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark		Monitored, elicited by investigator
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil		Monitored, elicited by investigator, reported by patient
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY		NR
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan		NR
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan		NR
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland		NR
Kim SH et al., 2004[21] Pamidronate Asia		NR
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP		Monitored, reported by patient
Lindsay R et al., 1997[23] Estrogen, PTH US		Monitored, elicited by investigator

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 12-13: Results continued, Methods of AE assessment

Author, Year, Drug, Country, Trial name	Results - 6	Methods of adverse events assessment
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Number of people with fracture: tibia at 12 months: Alendronate+Estrogen vs Estrogen 0.0% vs 0.5% OR = 0.13 (95% CI 0.00, 6.42) Number of people with fracture: wrist at 12 months: Alendronate+Estrogen vs Estrogen 0.5% vs 0.5% OR = 0.94 (95% CI 0.06, 15.11)	Elicited by investigator
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY		Elicited by investigator, reported by patient
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy		NR
Ninkovic M et al., 2002[27] Pamidronate UK		NR
Ravn P et al., 1996[28] Ibandronate Western Europe		Monitored, reported by patient
Recker R et al., 2004[29] Ibandronate US, Western Europe		Monitored
Reid IR et al., 1994[30] Pamidronate Australia/NZ		Monitored
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia		NR
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa		Elicited by investigator
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI		Monitored, elicited by investigator, reported by patient
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK		Monitored

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 14: AEs Reported

Author, Year, Drug, Country, Trial name	Adverse events reported
Aris RM et al., 2000[1] Pamidronate US	Control vs Pamidronate: Bone pain: 0.0%(0/18) vs 0.0%(0/16) Cellulitis: 0.0%(0/18) vs 0.0%(0/16) Fever: 0.0%(0/18) vs 0.0%(0/16) Hypocalcemia: 0.0%(0/18) vs 0.0%(0/16) Mild hypervitaminosis D: 0.0%(0/18) vs 18.8%(3/16) Thrombophlebitis: 0.0%(0/18) vs 0.0%(0/16)
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	Alendronate vs Teriparatide: Death from cardiac arrest: 0.0%(0/73) vs 1.4%(1/73) Elevations in serum calcium: 2.7%(2/73) vs 38.4%(28/73) Leg cramps: 0.0%(0/73) vs 8.2%(6/73) New or worsened back pain: 19.2%(14/73) vs 5.5%(4/73) Positive test for antiteriparatide antibodies: 0.0%(0/73) vs 4.1%(3/73)
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	Placebo vs Alendronate vs CEE vs Combination: Any adverse experience: 90.0%(45/50) vs 87.0%(80/92) vs 90.2%(129/143) vs 92.9%(130/140) Any serious adverse experience: 10.0%(5/50) vs 14.1%(13/92) vs 11.9%(17/143) vs 13.6%(19/140) Abdominal pain: 4.0%(2/50) vs 7.6%(7/92) vs 6.3%(9/143) vs 7.9%(11/140) Any upper gastrointestinal adverse experiences: 22.0%(11/50) vs 27.2%(25/92) vs 30.1%(43/143) vs 33.6%(47/140) Dyspepsia: 6.0%(3/50) vs 7.6%(7/92) vs 6.3%(9/143) vs 5.7%(8/140) Esophageal irritation: 4.0%(2/50) vs 5.4%(5/92) vs 3.5%(5/143) vs 3.6%(5/140) Peptic ulcer: 0.0%(0/50) vs 0.0%(0/92) vs 0.0%(0/143) vs 1.4%(2/140)
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Placebo vs Ibandronate 20mg vs Ibandronate 2.5mg: Any adverse event: 88.9%(867/975) vs 91.9%(898/977) vs 90.9%(888/977) Any serious adverse event: 21.6%(211/975) vs 25.3%(247/977) vs 24.1%(235/977) Any adverse event leading to death: 1.0%(10/975) vs 0.8%(8/977) vs 1.1%(11/977) Any drug related adverse event: 17.9%(175/975) vs 18.5%(181/977) vs 19.9%(194/977) Any drug related serious adverse event: 0.0%(0/975) vs 0.7%(7/977) vs 0.3%(3/977) Belching: 0.2%(2/975) vs 0.5%(5/977) vs 0.4%(4/977) Duodenal ulcer: 0.9%(9/975) vs 0.1%(1/977) vs 0.1%(1/977) Dyspepsia: 9.1%(89/975) vs 9.0%(88/977) vs 11.4%(111/977) Esophageal ulcer: 0.1%(1/975) vs 0.1%(1/977) vs 0.2%(2/977) Espohageal stenosis: 0.1%(1/975) vs 0.0%(0/977) vs 0.2%(2/977) Espophagitis: 1.0%(10/975) vs 1.0%(10/977) vs 1.5%(15/977) GI pain: 2.6%(25/975) vs 2.5%(24/977) vs 1.9%(19/977) Gastritis: 2.3%(22/975) vs 1.2%(12/977) vs 2.3%(22/977) Gastroenteritis: 5.5%(54/975) vs 6.3%(62/977) vs 5.5%(54/977) Nausea: 6.3%(61/975) vs 6.4%(63/977) vs 4.2%(41/977) Stomach ulcer: 0.6%(6/975) vs 0.5%(5/977) vs 0.3%(3/977) Vomiting: 2.5%(24/975) vs 2.8%(27/977) vs 3.0%(29/977)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 14: AEs Reported

Author, Year, Drug, Country, Trial name	Adverse events reported
Coco M et al., 2003[5] Pamidronate US	No adverse events reported.
Cosman F et al., 2001[6] Estrogen, PTH US	HRT vs HRT + PTH: Nodules at injection site: 0.0%(0/25) vs 7.4%(2/27)
Cosman F et al., 2005[7] Alendronate, PTH US	Alendronate 70mg + cyclical PTH vs Alendronate 70mg + daily PTH vs Alendronate 70mg weekly: Abnormal CBD: 10.0%(4/40) vs 11.6%(5/43) vs 4.7%(2/43) Cardiac symptoms: 7.5%(3/40) vs 11.6%(5/43) vs 7.0%(3/43) Death from complications of aortic-valve surgery: 0.0%(0/40) vs 0.0%(0/43) vs 2.3%(1/43) GI effects: 17.5%(7/40) vs 20.9%(9/43) vs 9.3%(4/43) Generalized fatigue: 7.5%(3/40) vs 4.7%(2/43) vs 0.0%(0/43) Increase liver function tests: 0.0%(0/40) vs 2.3%(1/43) vs 4.7%(2/43) Increase serum creatinine: 0.0%(0/40) vs 0.0%(0/43) vs 0.0%(0/43) Increase total serum calcium: 2.5%(1/40) vs 2.3%(1/43) vs 0.0%(0/43) Increased urinary calcium: 15.0%(6/40) vs 34.9%(15/43) vs 7.0%(3/43) Musculoskeletal symptoms: 10.0%(4/40) vs 23.3%(10/43) vs 4.7%(2/43) Redness at injection site: 15.0%(6/40) vs 2.3%(1/43) vs 0.0%(0/43) Vascular symptoms: 2.5%(1/40) vs 4.7%(2/43) vs 0.0%(0/43)
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	Etidronate vs Risedronate: Abdominal distension: 1.7%(2/117) vs 5.9%(7/118) Abnormal lab data: 12.0%(14/117) vs 9.3%(11/118) Any adverse event: 81.2%(95/117) vs 81.4%(96/118) Cardiovascular events: 0.9%(1/117) vs 2.5%(3/118) Constipation: 6.0%(7/117) vs 3.4%(4/118) Dermatologic events: 2.6%(3/117) vs 2.5%(3/118) Epigastric pain: 7.7%(9/117) vs 7.6%(9/118) GI events: 19.7%(23/117) vs 22.9%(27/118) Nausea: 0.9%(1/117) vs 3.4%(4/118) Neurologic events: 4.3%(5/117) vs 4.2%(5/118)
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	No adverse events reported.

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 14: AEs Reported

Author, Year, Drug, Country, Trial name	Adverse events reported
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	Placebo vs ALN vs HRT vs HRT + ALN: Bloating: 2.2%(2/93) vs 4.3%(4/93) vs 9.7%(9/93) vs 5.3%(5/94) Breast tenderness: 17.2%(16/93) vs 23.7%(22/93) vs 55.9%(52/93) vs 53.2%(50/94) Chest pain: 14.0%(13/93) vs 17.2%(16/93) vs 10.8%(10/93) vs 9.6%(9/94) Deep venous thrombosis: 0.0%(0/93) vs 1.1%(1/93) vs 2.2%(2/93) vs 0.0%(0/94) Dysphagia: 2.2%(2/93) vs 3.2%(3/93) vs 1.1%(1/93) vs 2.1%(2/94) Endometrial biopsy: 1.1%(1/93) vs 2.2%(2/93) vs 12.9%(12/93) vs 11.7%(11/94) Esophagitis: 22.6%(21/93) vs 28.0%(26/93) vs 18.3%(17/93) vs 21.3%(20/94) Falls: 45.2%(42/93) vs 55.9%(52/93) vs 47.3%(44/93) vs 52.1%(49/94) Heartburn: 16.1%(15/93) vs 18.3%(17/93) vs 11.8%(11/93) vs 17.0%(16/94) High blood pressure: 3.2%(3/93) vs 5.4%(5/93) vs 6.5%(6/93) vs 2.1%(2/94) Hospitialization: 28.0%(26/93) vs 36.6%(34/93) vs 43.0%(40/93) vs 34.0%(32/94) Indigestion: 4.3%(4/93) vs 6.5%(6/93) vs 5.4%(5/93) vs 1.1%(1/94) Menstrual cramps: 0.0%(0/93) vs 0.0%(0/93) vs 6.5%(6/93) vs 5.3%(5/94) Menstrual spotting: 9.7%(9/93) vs 7.5%(7/93) vs 31.2%(29/93) vs 33.0%(31/94) Myocardial infarction: 1.1%(1/93) vs 2.2%(2/93) vs 0.0%(0/93) vs 1.1%(1/94) Peripheral edema: 12.9%(12/93) vs 9.7%(9/93) vs 14.0%(13/93) vs 11.7%(11/94) Weight gain: 8.6%(8/93) vs 6.5%(6/93) vs 8.6%(8/93) vs 8.5%(8/94)
Grotz W et al., 2001[11] Ibandronate Germany	Placebo vs Ibandronate: Death: 5.0%(2/40) vs 7.5%(3/40) Side effects in temporal relation to ibandronate administration (bone pain, flatulence): 0.0%(0/40) vs 7.5%(3/40)
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Alendronate vs Etidronate: GI symptoms: 6.3%(1/16) vs 12.5%(2/16) Minor gastric symptoms: 12.5%(2/16) vs 6.3%(1/16)
Harris ST et al., 2001[13] Estrogen, Resindronate US	CE + Placebo vs CE + Risedronate: Serious adverse events: 8.8%(23/261) vs 5.3%(14/263) All upper gastrointestinal (GI) adverse events: 16.5%(43/261) vs 16.4%(43/263) Breast fibrocyst: 13.4%(35/261) vs 8.7%(23/263) Breast pain: 30.3%(79/261) vs 27.4%(72/263) Constipation: 1.9%(5/261) vs 6.5%(17/263) Diarrhea: 4.2%(11/261) vs 7.6%(20/263) Esophagitis: 0.8%(2/261) vs 0.4%(1/263) Gastric or duodenal ulcer: 1.1%(3/261) vs 0.0%(0/263) Gastritis: 0.8%(2/261) vs 1.5%(4/263) Hypertension: 5.7%(15/261) vs 2.7%(7/263) Moderate to severe upper GI adverse events: 8.0%(21/261) vs 6.8%(18/263) Peptic ulcer: 0.0%(0/261) vs 0.4%(1/263) Vaginal hemorrhage: 13.4%(35/261) vs 8.7%(23/263)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 14: AEs Reported

Author, Year, Drug, Country, Trial name	Adverse events reported
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	Number of adverse events not reported.
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	Placebo vs Alendronate 5mg vs Alendronate 2.5mg vs Estrogen-progestin: Cardiovascular system adverse event: 9.4%(47/502) vs 9.8%(49/498) vs 10.0%(50/499) vs 13.6%(15/110) Digestive sytem adverse event: 52.4%(263/502) vs 53.2%(265/498) vs 51.7%(258/499) vs 50.9%(56/110) Musculoskeletal system adverse event: 59.6%(299/502) vs 61.8%(308/498) vs 63.9%(319/499) vs 56.4%(62/110) Nervous system/pyschiatric adverse event: 31.1%(156/502) vs 32.7%(163/498) vs 29.9%(149/499) vs 32.7%(36/110) Respiratory system adverse event: 77.1%(387/502) vs 74.3%(370/498) vs 75.0%(374/499) vs 70.9%(78/110) Skin adverse event: 33.1%(166/502) vs 32.5%(162/498) vs 31.9%(159/499) vs 28.2%(31/110) Urogenital system adverse event: 33.5%(168/502) vs 32.9%(164/498) vs 36.3%(181/499) vs 44.5%(49/110)
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	Placebo vs Alendronate 70 mg vs Risedronate 5 mg: Any adverse effects: 70.4%(76/108) vs 77.2%(169/219) vs 76.1%(169/222) Any upper gastrointestinal: 26.9%(29/108) vs 28.3%(62/219) vs 27.5%(61/222) Deglutition disorder: 0.0%(0/108) vs 0.0%(0/219) vs 0.5%(1/222) Dysphagia: 0.0%(0/108) vs 0.9%(2/219) vs 0.0%(0/222) Gastric ulcer: 0.0%(0/108) vs 0.0%(0/219) vs 0.5%(1/222) Oesophagitis: 0.0%(0/108) vs 1.4%(3/219) vs 0.9%(2/222) One or more Oesophageal adverse events: 0.0%(0/108) vs 2.3%(5/219) vs 1.8%(4/222) One or more PUBs adverse events: 0.0%(0/108) vs 0.0%(0/219) vs 0.5%(1/222) Reflux oesophagitis: 0.0%(0/108) vs 0.0%(0/219) vs 0.5%(1/222) Serious upper gastrointestinal: 1.9%(2/108) vs 0.5%(1/219) vs 0.0%(0/222)
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	HRT vs Alfacalcidol vs Calcitonin vs Control vs Etidronate vs Vit K: Bleeding: 3.0%(2/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 0.0%(0/66) Breast tenderness: 1.5%(1/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 0.0%(0/66) GI symptoms: 0.0%(0/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 1.5%(1/66) vs 0.0%(0/66)
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	No adverse events reported.
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	No adverse events reported.
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	CA/Vit D/HRT vs Pamidronate: Death: 32.7%(16/49) vs 26.0%(13/50) Secondary cancer: 0.0%(0/49) vs 4.0%(2/50)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 14: AEs Reported

Author, Year, Drug, Country, Trial name	Adverse events reported
Kim SH et al., 2004[21] Pamidronate Asia	Placebo vs Pamidronate: Hypocalcemia: 0.0%(0/25) vs 4.0%(1/25)
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	Etidronate vs Risedronate: Any adverse event: 93.1%(255/274) vs 91.2%(249/273) Any drug related adverse event: 32.8%(90/274) vs 31.5%(86/273) Abdominal distension: 2.2%(6/274) vs 0.7%(2/273) Abnormal laboratory parameters: 7.3%(20/274) vs 10.6%(29/273) Constipation: 2.2%(6/274) vs 0.7%(2/273) Epigastric pain: 6.9%(19/274) vs 6.2%(17/273) Gastrointestinal disorders: 19.7%(54/274) vs 17.6%(48/273) General disorders: 1.5%(4/274) vs 2.6%(7/273) Musculoskeletal and connective tissue disorders: 2.9%(8/274) vs 1.5%(4/273) Nausea: 1.8%(5/274) vs 2.2%(6/273) Nervous system disorders: 3.3%(9/274) vs 2.9%(8/273) Skin and subcutaneous disorders: 2.9%(8/274) vs 2.2%(6/273)
Lindsay R et al., 1997[23] Estrogen, PTH US	hPTH (1–34) + oestrogen vs Oestrogen: Back pain: 5.9%(1/17) vs 0.0%(0/17) Breast cancer: 5.9%(1/17) vs 0.0%(0/17) Otosclerosis: 5.9%(1/17) vs 0.0%(0/17) Subcutaneous nodules at injection site: 11.8%(2/17) vs 0.0%(0/17) Urinary tract infection & possible renal stone: 5.9%(1/17) vs 0.0%(0/17)
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Alendronate 10mg + HRT vs Placebo + HRT: Serious adverse event: 6.1%(13/214) vs 7.9%(17/214) Back pain: 9.8%(21/214) vs 3.3%(7/214) GI adverse events: 10.3%(22/214) vs 10.3%(22/214)
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	Alendronate 70mg vs Raloxifene 60mg: Any adverse event: 73.5%(164/223) vs 74.2%(173/233) Any serious adverse event: 4.9%(11/223) vs 6.9%(16/233) Abdominal pain: 3.1%(7/223) vs 1.7%(4/233) Any UGI adverse event: 17.0%(38/223) vs 15.5%(36/233) Any drug related UGI adverse event: 10.8%(24/223) vs 10.3%(24/233) Any drug related adverse event: 25.6%(57/223) vs 26.6%(62/233) Any drug related vasomotor adverse event: 4.0%(9/223) vs 6.9%(16/233) Any vasomotor adverse event: 4.5%(10/223) vs 7.3%(17/233) Deep venous thrombosis: 0.0%(0/223) vs 0.4%(1/233) Dyspepsia: 3.1%(7/223) vs 2.6%(6/233) Heartburn: 2.7%(6/223) vs 1.7%(4/233) Nausea: 5.8%(13/223) vs 5.2%(12/233)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 14: AEs Reported

Author, Year, Drug, Country, Trial name	Adverse events reported
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	No adverse events reported.
Ninkovic M et al., 2002[27] Pamidronate UK	No pamidronate vs Pamidronate: Diarrhea: 0.0%(0/54) vs 2.2%(1/45) Symptomatic fever: 0.0%(0/54) vs 6.7%(3/45)
Ravn P et al., 1996[28] Ibandronate Western Europe	Placebo vs Ibandronate 0.25mg vs Ibandronate 0.5mg vs Ibandronate 1.0mg vs Ibandronate 2.5mg vs Ibandronate 5.0mg: Breast cancer: 0.0%(0/30) vs 0.0%(0/30) vs 3.3%(1/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) Cerebral hemorrhage leading to death: 3.3%(1/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) Death from suspected MI: 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 3.3%(1/30) vs 0.0%(0/30) Diarrhea only: 6.7%(2/30) vs 20.0%(6/30) vs 16.7%(5/30) vs 6.7%(2/30) vs 6.7%(2/30) vs 33.3%(10/30) Infection: 3.3%(1/30) vs 3.3%(1/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 3.3%(1/30) vs 0.0%(0/30) Non-serious GI events: 50.0%(15/30) vs 50.0%(15/30) vs 83.3%(25/30) vs 30.0%(9/30) vs 23.3%(7/30) vs 63.3%(19/30) Stenosis of iliac artery: 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 3.3%(1/30) vs 0.0%(0/30) Tachycardia: 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 0.0%(0/30) vs 3.3%(1/30)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 14: AEs Reported

Author, Year, Drug, Country, Trial name	Adverse events reported
Recker R et al., 2004[29] Ibandronate US, Western Europe	Placebo vs Ibandronate 0.5 mg vs Ibandronate 1 mg: At least one adverse event: 94.1%(893/949) vs 94.3%(896/950) vs 95.2%(915/961) At least one serious adverse event: 26.7%(253/949) vs 25.2%(239/950) vs 23.2%(223/961) Cardiovascular system adverse event: 25.3%(240/949) vs 24.7%(235/950) vs 22.9%(220/961) Cardiovascular system serious adverse event: 7.2%(68/949) vs 6.6%(63/950) vs 6.9%(66/961) Cataract: 0.0%(0/949) vs 0.1%(1/950) vs 0.0%(0/961) Cerebral infarction: 0.0%(0/949) vs 0.0%(0/950) vs 0.1%(1/961) Death: 0.0%(0/949) vs 0.0%(0/950) vs 0.0%(0/961) Digestive system adverse event: 39.9%(379/949) vs 40.5%(385/950) vs 38.6%(371/961) Digestive system serious adverse event: 4.4%(42/949) vs 4.3%(41/950) vs 4.0%(38/961) Dyspepsia: 0.1%(1/949) vs 0.0%(0/950) vs 0.0%(0/961) Eczema: 0.1%(1/949) vs 0.0%(0/950) vs 0.0%(0/961) Endocrine system serious adverse event: 0.1%(1/949) vs 0.1%(1/950) vs 0.2%(2/961) Hemic and lymphatic system adverse event: 6.5%(62/949) vs 8.2%(78/950) vs 6.3%(61/961) Hemic and lymphatic system serious adverse event: 0.5%(5/949) vs 0.4%(4/950) vs 0.6%(6/961) Hypertension: 0.1%(1/949) vs 0.0%(0/950) vs 0.0%(0/961) Injection site reactions: 0.1%(1/949) vs 2.3%(22/950) vs 2.5%(24/961) Metabolic and nutritional disorders adverse event: 15.5%(147/949) vs 17.3%(164/950) vs 16.6%(160/961) Metabolic and nutritional disorders serious adverse event: 0.2%(2/949) vs 0.7%(7/950) Metabolic and nutritional disordersserious adverse event: 0.3%(3/961) Musculoskeletal system adverse event: 51.4%(488/949) vs 52.3%(497/950) vs 50.5%(485/961) Musculoskeletal system serious adverse event: 6.8%(65/949) vs 6.0%(57/950) vs 4.7%(45/961) Myalgia: 3.4%(32/949) vs 5.2%(49/950) vs 7.1%(68/961) Nervous system adverse event: 26.8%(254/949) vs 25.2%(239/950) vs 26.0%(250/961) Nervous system serious adverse event: 2.3%(22/949) vs 1.2%(11/950) vs 2.0%(19/961) Respiratory system adverse event: 53.2%(505/949) vs 53.7%(510/950) vs 52.9%(508/961) Respiratory system serious adverse event: 2.0%(19/949) vs 2.8%(27/950) vs 2.0%(19/961) Skin and appendages adverse event: 23.4%(222/949) vs 19.4%(184/950) vs 19.6%(188/961) Skin and appendages serious adverse event: 2.7%(26/949) vs 2.0%(19/950) vs 2.2%(21/961) Special senses adverse event: 17.1%(162/949) vs 15.8%(150/950) vs 15.3%(147/961) Special senses serious adverse event: 0.5%(5/949) vs 1.1%(10/950) vs 0.7%(7/961) Urogenital system adverse event: 17.2%(163/949) vs 17.8%(169/950) vs 19.3%(185/961) Urogenital system serious adverse event: 2.1%(20/949) vs 1.9%(18/950) vs 1.9%(18/961) Whole body adverse event: 56.1%(532/949) vs 56.1%(533/950) vs 58.6%(563/961) Whole body serious adverse event: 4.5%(43/949) vs 4.0%(38/950) vs 3.5%(34/961)
Reid IR et al., 1994[30] Pamidronate Australia/NZ	Placebo vs Pamidronate: Duodenal ulcer: 0.0%(0/22) vs 3.8%(1/26) Duodenitis: 4.5%(1/22) vs 0.0%(0/26) Gastrointestinal adverse events: 54.5%(12/22) vs 57.7%(15/26) Nausea: 18.2%(4/22) vs 26.9%(7/26)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 14: AEs Reported

Author, Year, Drug, Country, Trial name	Adverse events reported
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	Placebo vs ZA 1x 4 mg vs ZA 2x 2 mg vs ZA 4x 0.25 mg vs ZA 4x 0.50 mg vs ZA 4x 1 mg: Women with an adverse event: 76.3%(45/59) vs 90.0%(54/60) vs 91.8%(56/61) vs 86.7%(52/60) vs 86.2%(50/58) vs 94.3%(50/53) Any serious adverse event: 5.1%(3/59) vs 10.0%(6/60) vs 8.2%(5/61) vs 6.7%(4/60) vs 6.9%(4/58) vs 13.2%(7/53) Arthralgia: 15.3%(9/59) vs 8.3%(5/60) vs 24.6%(15/61) vs 15.0%(9/60) vs 13.8%(8/58) vs 17.0%(9/53) Influenza-like illness: 6.8%(4/59) vs 15.0%(9/60) vs 16.4%(10/61) vs 1.7%(1/60) vs 6.9%(4/58) vs 3.8%(2/53) Myalgia: 1.7%(1/59) vs 10.0%(6/60) vs 16.4%(10/61) vs 20.0%(12/60) vs 10.3%(6/58) vs 13.2%(7/53) Nausea: 5.1%(3/59) vs 13.3%(8/60) vs 9.8%(6/61) vs 5.0%(3/60) vs 6.9%(4/58) vs 9.4%(5/53) Pyrexia: 3.4%(2/59) vs 15.0%(9/60) vs 19.7%(12/61) vs 10.0%(6/60) vs 8.6%(5/58) vs 13.2%(7/53)
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	Placebo vs Estrogen 0.625mg/d vs Raloxifene 150mg/d vs Raloxifene 60mg/d: Breast enlargement: 0.7%(1/152) vs 4.4%(7/158) vs 0.6%(1/157) vs 0.7%(1/152) Breast pain: 6.6%(10/152) vs 15.8%(25/158) vs 5.7%(9/157) vs 7.2%(11/152) Hernia: 4.6%(7/152) vs 0.6%(1/158) vs 0.6%(1/157) vs 3.3%(5/152) Hot flashes: 27.0%(41/152) vs 10.8%(17/158) vs 44.6%(70/157) vs 33.6%(51/152) Leg cramps: 1.3%(2/152) vs 3.2%(5/158) vs 8.9%(14/157) vs 9.9%(15/152) MI: 0.0%(0/152) vs 0.6%(1/158) vs 0.6%(1/157) vs 0.7%(1/152) Urinary incontinense: 1.3%(2/152) vs 7.0%(11/158) vs 0.6%(1/157) vs 0.7%(1/152)
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	ALN vs RSN: Any adverse event: 75.8%(394/520) vs 74.9%(399/533) Serious adverse event: 8.7%(45/520) vs 7.7%(41/533) Any UGI adverse event: 22.3%(116/520) vs 19.9%(106/533)
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	HRT vs HRT and etidronate vs Control group vs Etidronate: Death due to myocardial infarction: 0.0%(0/18) vs 0.0%(0/19) vs 0.0%(0/18) vs 5.9%(1/17) Estrogen-related adverse effects: 16.7%(3/18) vs 10.5%(2/19) vs 0.0%(0/18) vs 0.0%(0/17) Nausea: 0.0%(0/18) vs 0.0%(0/19) vs 0.0%(0/18) vs 35.3%(6/17)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 15: Withdrawals

Author, Year, Drug, Country, Trial name	Total withdrawals Withdrawals due to adverse events
Aris RM et al., 2000[1] Pamidronate US	Control vs Pamidronate: Withdrawals: Not reported Withdrawals due to adverse events: NR vs 0.0%(0/16)
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	Alendronate vs Teriparatide: Withdrawals: 21.9%(16/73) vs 30.1%(22/73) Withdrawals due to adverse events: 9.6%(7/73) vs 19.2%(14/73)
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	Alendronate vs CEE vs Combination vs Placebo: Withdrawals: 15.2%(14/92) vs 15.4%(22/143) vs 13.6%(19/140) vs 18.0%(9/50) Withdrawals due to adverse events: 6.5%(6/92) vs 9.8%(14/143) vs 9.3%(13/140) vs 10.0%(5/50)
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Ibandronate 2.5mg vs Ibandronate 20mg vs Placebo: Withdrawals: 34.2%(334/977) vs 32.8%(320/977) vs 36.3%(354/975) Withdrawals due to adverse events: 17.9%(175/977) vs 18.2%(178/977) vs 18.5%(180/975)
Coco M et al., 2003[5] Pamidronate US	Calcium vs Pamidronate: Withdrawals: 22.2%(8/36) vs 13.9%(5/36) Withdrawals due to adverse events: Not reported
Cosman F et al., 2001[6] Estrogen, PTH US	HRT vs HRT + PTH: Withdrawals: 28.0%(7/25) vs 14.8%(4/27) Withdrawals due to adverse events: Not reported
Cosman F et al., 2005[7] Alendronate, PTH US	Alendronate 70mg + cyclical PTH vs Alendronate 70mg + daily PTH vs Alendronate 70mg weekly: Withdrawals: 15.0%(6/40) vs 11.6%(5/43) vs 16.3%(7/43) Withdrawals due to adverse events: 15.0%(6/40) vs 11.6%(5/43) vs 9.3%(4/43)
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	Etidronate vs Risedronate: Withdrawals: 12.8%(15/117) vs 16.9%(20/118) Withdrawals due to adverse events: 6.0%(7/117) vs 6.8%(8/118)
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	Calcidiol vs Calcitonin vs Etidronate: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	ALN vs HRT vs HRT + ALN vs Placebo: Withdrawals: 8.6%(8/93) vs 9.7%(9/93) vs 9.6%(9/94) vs 10.8%(10/93) Withdrawals due to adverse events: 2.2%(2/93) vs 2.2%(2/93) vs 0.0%(0/94) vs 2.2%(2/93)
Grotz W et al., 2001[11] Ibandronate Germany	Ibandronate vs Placebo: Withdrawals: 10.0%(4/40) vs 10.0%(4/40) Withdrawals due to adverse events: 7.5%(3/40) vs 5.0%(2/40)
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Alendronate vs Etidronate: Withdrawals: 18.8%(3/16) vs 18.8%(3/16) Withdrawals due to adverse events: 6.3%(1/16) vs 18.8%(3/16)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 15: Withdrawals

Author, Year, Drug, Country, Trial name	Total withdrawals Withdrawals due to adverse events
Harris ST et al., 2001[13] Estrogen, Resindronate US	CE + Placebo vs CE + Risedronate: Withdrawals: 29.1%(76/261) vs 24.7%(65/263) Withdrawals due to adverse events: 18.8%(49/261) vs 10.3%(27/263)
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	hPTH vs hPTH + Calcitonin: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	Alendronate 2.5mg vs Alendronate 5mg vs Estrogen-progestin vs Placebo: Withdrawals: 20.4%(102/499) vs 18.5%(92/498) vs 17.3%(19/110) vs 18.5%(93/502) Withdrawals due to adverse events: 8.4%(42/499) vs 5.2%(26/498) vs 13.6%(15/110) vs 5.6%(28/502)
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	Alendronate 70 mg vs Risedronate 5 mg vs Placebo: Withdrawals: 21.5%(47/219) vs 19.8%(44/222) vs 17.6%(19/108) Withdrawals due to adverse events: 14.2%(31/219) vs 14.0%(31/222) vs 11.1%(12/108)
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	HRT vs Alfacalcidol vs Calcitonin vs Control vs Etidronate vs Vit K: Withdrawals: 6.1%(4/66) vs 4.5%(3/66) vs 6.1%(4/66) vs 9.1%(6/66) vs 6.1%(4/66) vs 4.5%(3/66) Withdrawals due to adverse events: 4.5%(3/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 0.0%(0/66) vs 1.5%(1/66) vs 0.0%(0/66)
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	Alendronate vs Etidronate: Withdrawals: 0.0%(0/25) vs 0.0%(0/25) Withdrawals due to adverse events: 0.0%(0/25) vs 0.0%(0/25)
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	Etidronate vs Etidronate + Alendronate: Withdrawals: Not reported Withdrawals due to adverse events: 0.0%(0/20) vs 0.0%(0/20)
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	CA/Vit D/HRT vs Pamidronate: Withdrawals: 32.7%(16/49) vs 34.0%(17/50) Withdrawals due to adverse events: 30.6%(15/49) vs 30.0%(15/50)
Kim SH et al., 2004[21] Pamidronate Asia	Pamidronate vs Placebo: Withdrawals: 0.0%(0/25) vs 20.0%(5/25) Withdrawals due to adverse events: Not reported
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	Etidronate vs Risedronate: Withdrawals: 30.7%(84/274) vs 26.7%(73/273) Withdrawals due to adverse events: 21.2%(58/274) vs 13.9%(38/273)
Lindsay R et al., 1997[23] Estrogen, PTH US	hPTH (1–34) + oestrogen vs Oestrogen: Withdrawals: 23.5%(4/17) vs 0.0%(0/17) Withdrawals due to adverse events: 11.8%(2/17) vs 0.0%(0/17)
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Alendronate 10mg + HRT vs Placebo + HRT: Withdrawals: 5.1%(11/214) vs 10.7%(23/214) Withdrawals due to adverse events: 2.3%(5/214) vs 5.1%(11/214)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Column 15: Withdrawals

Author, Year, Drug, Country, Trial name	Total withdrawals Withdrawals due to adverse events
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	Alendronate 70mg vs Raloxifene 60mg: Withdrawals: 19.7%(44/223) vs 17.2%(40/233) Withdrawals due to adverse events: 11.2%(25/223) vs 10.3%(24/233)
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Alendronate vs Clodronate vs Raloxifene vs Risedronate: Withdrawals: Not reported Withdrawals due to adverse events: Not reported
Ninkovic M et al., 2002[27] Pamidronate UK	No pamidronate vs Pamidronate: Withdrawals: 29.6%(16/54) vs 26.7%(12/45) Withdrawals due to adverse events: 25.9%(14/54) vs 13.3%(6/45)
Ravn P et al., 1996[28] Ibandronate Western Europe	Ibandronate 0.25mg vs Ibandronate 0.5mg vs Ibandronate 1.0mg vs Ibandronate 2.5mg vs Ibandronate 5.0mg vs Placebo: Withdrawals: 13.3%(4/30) vs 26.7%(8/30) vs 13.3%(4/30) vs 20.0%(6/30) vs 40.0%(12/30) vs 16.7%(5/30) Withdrawals due to adverse events: 6.7%(2/30) vs 10.0%(3/30) vs 3.3%(1/30) vs 3.3%(1/30) vs 3.3%(1/30) vs 13.3%(4/30)
Recker R et al., 2004[29] Ibandronate US, Western Europe	Ibandronate 0.5 mg vs Ibandronate 1 mg vs Placebo: Withdrawals: 16.1%(153/950) vs 19.5%(187/961) vs 17.2%(163/949) Withdrawals due to adverse events: 8.1%(77/950) vs 10.9%(105/961) vs 7.5%(71/949)
Reid IR et al., 1994[30] Pamidronate Australia/NZ	Pamidronate vs Placebo: Withdrawals: 19.2%(5/26) vs 36.4%(8/22) Withdrawals due to adverse events: 11.5%(3/26) vs 22.7%(5/22)
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	Placebo vs ZA 1x 4 mg vs ZA 2x 2 mg vs ZA 4x 0.25 mg vs ZA 4x 0.50 mg vs ZA 4x 1 mg: Withdrawals: Not reported Withdrawals due to adverse events: 1.7%(1/59) vs 3.3%(2/60) vs 3.3%(2/61) vs 6.7%(4/60) vs 3.4%(2/58) vs 5.7%(3/53)
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	Estrogen 0.625mg/d vs Placebo vs Raloxifene 150mg/d vs Raloxifene 60mg/d: Withdrawals: 35.4%(56/158) vs 40.8%(62/152) vs 35.0%(55/157) vs 40.1%(61/152) Withdrawals due to adverse events: 15.8%(25/158) vs 16.4%(25/152) vs 19.1%(30/157) vs 19.1%(29/152)
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	ALN vs RSN: Withdrawals: 15.8%(82/520) vs 14.8%(79/533) Withdrawals due to adverse events: 6.3%(33/520) vs 6.4%(34/533)
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	HRT vs HRT and etidronate vs Control group vs Etidronate: Withdrawals: 16.7%(3/18) vs 21.1%(4/19) vs 22.2%(4/18) vs 17.6%(3/17) Withdrawals due to adverse events: 16.7%(3/18) vs 21.1%(4/19) vs 16.7%(3/18) vs 17.6%(3/17)

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 16-17: Notes

Author, Year, Drug, Country, Trial name	Screener notes	Long form notes
Aris RM et al., 2000[1] Pamidronate US		DROPOUTS DESCRIBED BUT NEVER STATED WHICH ARM THEY BELONG TO.
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel		STUDY ENDED EARLY SECONDARY ADVERSE EVENTS (OSTEOSARCOMA) IN RATS
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP		
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE		
Coco M et al., 2003[5] Pamidronate US		CALCITRIOL AND CALCIUM GIVEN TO MAINTAIN SERUM CALCIUM BETWEEN 8.5 AND 10.5 MG IDL
Cosman F et al., 2001[6] Estrogen, PTH US		
Cosman F et al., 2005[7] Alendronate, PTH US		
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH		
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	SPECIAL POPULATION CARDIAC TRANSPLANTS	
Greenspan SL et al., 2003[10] Alendronate, Estrogen US		
Grotz W et al., 2001[11] Ibandronate Germany		IBANDRONATE GROUP GIVEN ONE DOSE OF 1 MG PRIOR TO TRANSPLANT THEN 2 MG AT 3, 6 AND 9 MONTHS
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	#4 PRIMARY BILIARY CIRRHOSIS	

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 16-17: Notes

Author, Year, Drug, Country, Trial name	Screener notes	Long form notes
Harris ST et al., 2001[13] Estrogen, Resindronate US		
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada		
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark		STRATUM 1 INCLUDED SUBJECTS WILLING TO BE RANDOMIZED TO ESTROGEN. STRATUM 2 INCLUDED SUBJECTS NOT WILLING TO BE RANDOMIZED TO ESTROGEN.
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil		
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY		
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan		
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan		
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland		
Kim SH et al., 2004[21] Pamidronate Asia		
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP		
Lindsay R et al., 1997[23] Estrogen, PTH US		SHORTAGE OF PTH OCCURRED 10 PTS HAD GAPS OF 1-8 WKS BETWEEN TREATMTS ALL PTS RECEIVED HPTH(1-34) FOR SHORT PERIOD(<5WK)
Lindsay R et al., 1999[24] Alendronate, Estrogen US		

Appendix C.1 Evidence Tables For Randomized Controlled Trials
Columns 16-17: Notes

Author, Year, Drug, Country, Trial name	Screener notes	Long form notes
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY		
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy		
Ninkovic M et al., 2002[27] Pamidronate UK		PAMIDRONATE GIVEN AS ONE TIME ONLY DOSE, THEN PATIENTS FOLLOWED FOR 12 MONTHS
Ravn P et al., 1996[28] Ibandronate Western Europe		
Recker R et al., 2004[29] Ibandronate US, Western Europe		
Reid IR et al., 1994[30] Pamidronate Australia/NZ		
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia		
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa		
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI		
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK		INTERVENTIONS - NUMBER COMPLETING/ ANALYZED IS FOR 4 YEAR DATA (2 YEAR DIFFERENT)

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Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 1-9: Article, Randomization, Concealment, Similar, Eligibility, Assessors, Providers, Patient, Adhere

Author, Year, Drug, Country, Trial name	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcomes assessors masked?	Care provider masked?	Patient masked?	Reporting of adherence and contamination?
Aris RM et al., 2000[1] Pamidronate US	Yes	Not described	Yes	Yes	Yes	No	No	NR /NR
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	Not described	Not described	Yes	Yes	Yes, but not described	Yes, but not described	Yes, but not described	Yes/NR
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	Yes	Not described	Yes	Yes	NR	Yes, but not described	Yes, but not described	NR /NR
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Yes	Not described	Yes	Yes	NR	Yes	Yes	NR /NR
Coco M et al., 2003[5] Pamidronate US	Yes	Not described	Yes	Yes	NR	NR	NR	NR /NR
Cosman F et al., 2001[6] Estrogen, PTH US	Yes	Not described	Yes	Yes	Yes	NR	NR	NR /NR
Cosman F et al., 2005[7] Alendronate, PTH US	Yes	Not described	Yes	Yes	Yes	No	No	Yes/NR

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 1-9: Article, Randomization, Concealment, Similar, Eligibility, Assessors, Providers, Patient, Adhere

Author, Year, Drug, Country, Trial name	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcomes assessors masked?	Care provider masked?	Patient masked?	Reporting of adherence and contamination?
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	Not described	Not described	Yes	Yes	Yes	Yes	Yes	NR /NR
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	Not described	Not described	Yes	Yes	NR	NR	NR	NR /NR
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NR /NR
Grotz W et al., 2001[11] Ibandronate Germany	Not described	No	Yes	Yes	Yes	NR	No	Yes/NR
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Yes	Not described	Yes	Yes	Yes	NR	NR	NR /NR
Harris ST et al., 2001[13] Estrogen, Resindronate US	Not described	Not described	Yes	Yes	NR	NR	NR	Yes/NR
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	Not described	Not described	Yes	Yes	NR	NR	NR	NR /NR
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	Not described	Not described	Yes	Yes	Yes	No	No	NR /NR

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 1-9: Article, Randomization, Concealment, Similar, Eligibility, Assessors, Providers, Patient, Adhere

Author, Year, Drug, Country, Trial name	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcomes assessors masked?	Care provider masked?	Patient masked?	Reporting of adherence and contamination?
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	Yes	Yes	Yes	Yes	NR	Yes	Yes	NR /NR
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	Not described	Not described	Yes	Yes	Yes	NR	NR	NR /NR
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	Not described	Not described	Yes	Yes	NR	NR	No	NR /NR
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	Not described	Not described	Yes	Yes	NR	NR	No	NR /NR
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	Not described	Not described	Yes	Yes	NR	No	No	NR /Yes
Kim SH et al., 2004[21] Pamidronate Asia	Not described	Not described	Yes	Yes	NR	NR	NR	NR /NR
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	Not described	Not described	Yes	Yes	Yes	NR	Yes	NR /NR

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 1-9: Article, Randomization, Concealment, Similar, Eligibility, Assessors, Providers, Patient, Adhere

Author, Year, Drug, Country, Trial name	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcomes assessors masked?	Care provider masked?	Patient masked?	Reporting of adherence and contamination?
Lindsay R et al., 1997[23] Estrogen, PTH US	Yes	Yes	Yes	Yes	Yes	NR	No	Yes/NR
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Not described	Not described	Yes	Yes	NR	NR	NR	NR /NR
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	Yes	Yes	Yes	Yes	Yes	NR	Yes	NR /NR
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Not described	Not described	NR	Yes	NR	No	No	NR /NR
Ninkovic M et al., 2002[27] Pamidronate UK	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes/Yes
Ravn P et al., 1996[28] Ibandronate Western Europe	Not described	Not described	Yes	Yes	NR	NR	NR	NR /NR
Recker R et al., 2004[29] Ibandronate US, Western Europe	Yes	Not described	Yes	Yes	Yes	Yes, but not described	Yes, but not described	NR /NR
Reid IR et al., 1994[30] Pamidronate Australia/NZ	Not described	Not described	Yes	Yes	NR	Yes	Yes	Yes/NR

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 1-9: Article, Randomization, Concealment, Similar, Eligibility, Assessors, Providers, Patient, Adhere

Author, Year, Drug, Country, Trial name	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcomes assessors masked?	Care provider masked?	Patient masked?	Reporting of adherence and contamination?
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	Not described	Yes	Yes	Yes	Yes	Yes	Yes	NR /NR
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	Yes	Not described	Yes	Yes	Yes	NR	NR	NR /NR
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	Yes	Not described	Yes	Yes	Yes	Yes	Yes	NR /NR
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	Yes	Yes	Yes	Yes	Yes	NR	No	NR /NR

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 10-13: Loss to FUP, ITT, Quality, Screened

Author, Year, Drug, Country, Trial name	Loss to follow-up: differential/high?	Intention-to-treat (ITT) analysis?	Quality rating (Jadad score)	Number screened/eligible/enrolled
Aris RM et al., 2000[1] Pamidronate US	No	Yes	3	44/37/37
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	No	Yes	4	265/149/149
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	No	Yes	4	NR/NR/425
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	NR	Yes	4	18447/NR/2946
Coco M et al., 2003[5] Pamidronate US	NR	No	2	112/98/72
Cosman F et al., 2001[6] Estrogen, PTH US	No	No	3	280/174/52
Cosman F et al., 2005[7] Alendronate, PTH US	No	No	3	1345/131/126

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 10-13: Loss to FUP, ITT, Quality, Screened

Author, Year, Drug, Country, Trial name	Loss to follow-up: differential/high?	Intention-to-treat (ITT) analysis?	Quality rating (Jadad score)	Number screened/eligible/enrolled
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	No	No	3	362/NR/235
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	NR	Yes	1	NR/NR/40
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	No	Yes	5	573/548/373
Grotz W et al., 2001[11] Ibandronate Germany	No	No	2	114/98/80
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	No	No	3	NR/NR/32
Harris ST et al., 2001[13] Estrogen, Resindronate US	NR	Yes	2	NR/NR/524
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	No	No	2	NR/NR/39
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	No	Yes	1	NR/NR/1609

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 10-13: Loss to FUP, ITT, Quality, Screened

Author, Year, Drug, Country, Trial name	Loss to follow-up: differential/high?	Intention-to-treat (ITT) analysis?	Quality rating (Jadad score)	Number screened/eligible/enrolled
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	No	Yes	5	1036/NR/549
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	No	Yes	2	739/NR/396
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	No	Yes	1	NR/NR/50
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	NR	No	1	NR/NR/40
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	No	No	1	115/108/99
Kim SH et al., 2004[21] Pamidronate Asia	No	Yes	2	NR/NR/50
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	No	No	4	NR/NR/547
Lindsay R et al., 1997[23] Estrogen, PTH US	No	Yes	3	NR/NR/40

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 10-13: Loss to FUP, ITT, Quality, Screened

Author, Year, Drug, Country, Trial name	Loss to follow-up: differential/high?	Intention-to-treat (ITT) analysis?	Quality rating (Jadad score)	Number screened/eligible/enrolled
Lindsay R et al., 1999[24] Alendronate, Estrogen US	No	Yes	1	1855/565/428
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	No	Yes	5	1200/508/456
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	NR	No	1	NR/NR/2000
Ninkovic M et al., 2002[27] Pamidronate UK	No	No	2	NR/NR/99
Ravn P et al., 1996[28] Ibandronate Western Europe	No	No	3	NR/821/180
Recker R et al., 2004[29] Ibandronate US, Western Europe	No	No	3	16632/NR/2862
Reid IR et al., 1994[30] Pamidronate Australia/NZ	No	No	4	NR/NR/61
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	NR	Yes	3	NR/NR/351

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 10-13: Loss to FUP, ITT, Quality, Screened

Author, Year, Drug, Country, Trial name	Loss to follow-up: differential/high?	Intention-to-treat (ITT) analysis?	Quality rating (Jadad score)	Number screened/eligible/enrolled
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	No	Yes	2	NR/1522/619
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	No	Yes	4	1759/NR/1053
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	No	No	3	350/NR/72

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 14-15: Run-in/washout, Naive

Author, Year, Drug, Country, Trial name	Exclusion criteria	Run-in/Washout	Class naive patients only?
Aris RM et al., 2000[1] Pamidronate US	Pregnancy, Renal insufficiency, Life expectancy <5 years, Graft Failure	NR NR	Not reported
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	Age > 85, Carcinoma or suspected carcinoma, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Malabsorption syndrome, Urolithiasis, Bisphosphonates, Calcitonin, Fluoride, Androgen, Estrogen agonists (including estrogen), Anabolic steroids, Corticoids/Glucocorticoids, Alcohol Abuse, Allergy to PTH, age<30, LS spine abnormalities prohibiting DEXA, previous PTH use	Run-in period reported NR	Yes
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	Cardiovascular disease, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Venous thromboembolic disease - Active, Venous thromboembolic disease - Ever, Bisphosphonates, Calcitonin, Fluoride, Vitamin D deficient, recent major upper GI mucosal erosive disease, Increased risk of breast cancer, Unexplained genital bleeding x 1 year, Fasting triglycerides >400mg/dL, Contraindication to HRT, HRT within last 6 months	NR NR	Not reported
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Metabolic bone disorder other than osteoporosis, Renal insufficiency, Bisphosphonates, Fluoride, Med known to affect skeleton, Diseases known to affect skeleton, > 2 fractures lumbar spine, Contraindication to Ca or Vitamin D, Hypercalcemia, Hypocalcemia, age <=55, age >= 80, T score<-5.0	NR NR	Yes
Coco M et al., 2003[5] Pamidronate US	Pregnancy	NR NR	Not reported
Cosman F et al., 2001[6] Estrogen, PTH US	Metabolic bone disorder other than osteoporosis, Nephrolithiasis	NR Washout period reported	Not reported
Cosman F et al., 2005[7] Alendronate, PTH US	Hypothyroidism, Hyperthyroidism, Hyperparathyroidism, Hypoparathroidism, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Nephrolithiasis, Anticonvulsants, Estrogen agonists (including estrogen), Corticoids/Glucocorticoids, Abnormal Urinary Calcium, Abnormal CBC	NR NR	No

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 14-15: Run-in/washout, Naive

Author, Year, Drug, Country, Trial name	Exclusion criteria	Run-in/Washout	Class naive patients only?
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	Age > 75, Carcinoma or suspected carcinoma, Cardiovascular disease, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Upper GI, LS spine abnormalities prohibiting DEXA, Med known to affect skeleton, Drug Hypersensitivity, History of Radiotherapy	NR NR	Not reported
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	Med known to affect skeleton, Hypogonadism	NR NR	Not reported
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	Carcinoma or suspected carcinoma, Hyperthyroidism, Hyperparathyroidism, Hepatic insufficiency, Renal insufficiency, Anticonvulsants, Bisphosphonates, Calcitonin, Hormone use, Corticoids/Glucocorticoids, Med known to affect skeleton, Contraindication to HRT, Contraindication to alendronate, BMD hip T score >0.0	Run-in period reported NR	Not reported
Grotz W et al., 2001[11] Ibandronate Germany	Kidney Pancreas Transplant	NR NR	Not reported
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Renal insufficiency, Upper GI, Bisphosphonates, Fluoride, Estrogen agonists (including estrogen), Corticoids/Glucocorticoids, Bilirubin >10mg/dL	NR NR	Yes
Harris ST et al., 2001[13] Estrogen, Resindronate US	Metabolic bone disorder other than osteoporosis, HRT, Med known to affect skeleton, Major systemic Disease, Abnl Pap, Significant Psychiatric disease, LS spine abnormalities prohibiting DEXA	NR NR	Not reported
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	Endocrine disease, Metabolic bone disorder other than osteoporosis, Bisphosphonates, Calcitonin, Corticoids/Glucocorticoids	NR NR	Not reported
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	Carcinoma or suspected carcinoma, Renal insufficiency, Upper GI, Bisphosphonates, Calcitonin, Fluoride, HRT, Med known to affect skeleton, phosphate binding antiacid, >60 years	NR NR	No

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 14-15: Run-in/washout, Naive

Author, Year, Drug, Country, Trial name	Exclusion criteria	Run-in/Washout	Class naive patients only?
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	Hypothyroidism, Hyperthyroidism, Hyperparathyroidism, Metabolic bone disorder other than osteoporosis, Bisphosphonates, Fluoride, HRT, Estrogen agonists (including estrogen), Corticoids/Glucocorticoids, LS spine abnormalities prohibiting DEXA, Vitamin D deficient, Severe Upper GI Sx, Severe Osteoporosis, age >90, age <60, Abnormal Urinary Calcium	NR NR	Not reported
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	Age > 75, Carcinoma or suspected carcinoma, Metabolic bone disorder other than osteoporosis, Med known to affect skeleton, bilateral hip fractures, mental condition that would preclude participation	NR NR	Not reported
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	Metabolic bone disorder other than osteoporosis, HRT, Estrogen agonists (including estrogen), Med known to affect skeleton	NR NR	Yes
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	Metabolic bone disorder other than osteoporosis, HRT, Estrogen agonists (including estrogen), Med known to affect skeleton, any lumbar vertebral fractures	NR NR	Yes
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	Renal insufficiency, Myeloma	NR NR	Not reported
Kim SH et al., 2004[21] Pamidronate Asia	Renal insufficiency, Bisphosphonates, bed rest	NR NR	Not reported
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	Cardiovascular disease, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Gastrointestinal disease, treatment with residronate or etidronate, Secondary Osteoperosis, radiographic findings that affect vertebral intensity, Med known to affect skeleton, malignancy under treatment with anti-tumor agents, radiation therapy to lumbar spine or pelvis	NR NR	Not reported

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 14-15: Run-in/washout, Naive

Author, Year, Drug, Country, Trial name	Exclusion criteria	Run-in/Washout	Class naive patients only?
Lindsay R et al., 1997[23] Estrogen, PTH US	Hypothyroidism, Hyperthyroidism, Hepatic insufficiency, Renal insufficiency, Nephrolithiasis, Secondary Osteoperosis	Run-in period reported NR	Not reported
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Hyperthyroidism, Metabolic bone disorder other than osteoporosis, Upper GI, Bisphosphonates, Calcitonin	Run-in period reported NR	Not reported
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Upper GI, Venous thromboembolic disease - Active, Venous thromboembolic disease - Ever, Bisphosphonates, Fluoride, Estrogen agonists (including estrogen), SERMS, Anabolic steroids, Corticoids/Glucocorticoids, LS spine abnormalities prohibiting DEXA, Immunosuppressants, Hypocalcemia, previous PTH use, Med known to affect skeleton, Breast Cancer, Uterine Cancer	NR NR	Not reported
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	NR	NR NR	Not reported
Ninkovic M et al., 2002[27] Pamidronate UK	Renal insufficiency, Bisphosphonates, retransplantation	NR NR	Yes
Ravn P et al., 1996[28] Ibandronate Western Europe	Age > 75, Bisphosphonates, Calcitonin, HRT, Diseases, conditions or treatments known to interfere with calcium metab	NR NR	Not reported
Recker R et al., 2004[29] Ibandronate US, Western Europe	Carcinoma or suspected carcinoma, Hypothyroidism, Hyperthyroidism, Hyperparathyroidism, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Gastrointestinal disease, Bisphosphonates, Calcitonin, Fluoride, HRT, Corticoids/Glucocorticoids, Alcohol Abuse, Med known to affect skeleton, Hypercalcemia, Hypocalcemia, Contraindication to Ca or Vitamin D, Cyclosporine	NR NR	Not reported

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 14-15: Run-in/washout, Naive

Author, Year, Drug, Country, Trial name	Exclusion criteria	Run-in/Washout	Class naive patients only?
Reid IR et al., 1994[30] Pamidronate Australia/NZ	Hypothyroidism, Hyperthyroidism, Hepatic insufficiency, Renal insufficiency, Anticonvulsants, Bisphosphonates, Calcitonin, Fluoride, HRT, Anabolic steroids, Corticoids/Glucocorticoids, Major systemic Disease, Hypercalcemia, Hypocalcemia	NR NR	Yes
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	Carcinoma or suspected carcinoma, Hypothyroidism, Hyperthyroidism, Hyperparathyroidism, Hypoparathroidism, Hepatic insufficiency, Metabolic bone disorder other than osteoporosis, Renal insufficiency, Bisphosphonates, Fluoride, HRT, Estrogen agonists (including estrogen), >1 Fracture, Vitamin D deficient, Med known to affect skeleton	NR NR	Yes
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	Hepatic insufficiency, Renal insufficiency, Venous thromboembolic disease - Ever, Anticonvulsants, Bisphosphonates, Calcitonin, Fluoride, Androgen, Estrogen agonists (including estrogen), Progestin, Lipid lowering agents, Vitamin D, Corticoids/Glucocorticoids, age <40, Endocrine disease requiring tx except thyroid, FSH<40, >4 drinks EtOH/day, >60 years, Breast Cancer, Estrogen Dependent CA, Any cancer except skin in last 5 years, Serious postmenopausal symptoms	NR NR	No
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	Metabolic bone disorder other than osteoporosis, Upper GI, Bisphosphonates, Fluoride, HRT, Estrogen agonists (including estrogen), Anabolic steroids, Corticoids/Glucocorticoids, Immunosuppressants, previous PTH use, Inability to remain 30min upright, Vitamin D deficient	NR NR	Not reported
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	Metabolic bone disorder other than osteoporosis, Bisphosphonates, Calcitonin, Fluoride, HRT, Anabolic steroids, Corticoids/Glucocorticoids, oopherectomy, Med known to affect skeleton	NR NR	Yes

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 16-18: Standard, Funding, Relevance

Author, Year, Drug, Country, Trial name	Control group standard of care?	Funding	Relevance?
Aris RM et al., 2000[1] Pamidronate US	Yes	Source: Government & Private; Role: NR	Limited
Body JJ et al., 2002[2] Alendronate, PTH US, Canada, Latin America, Western Europe, Israel	Yes	Source: Industry; Role: NR	Yes
Bone HG et al., 2000[3] Alendronate, Estrogen US ALENDRONATE ESTROGEN STUDY GRP	No	Source: Industry; Role: NR	Yes
Chesnut CH et al., 2004[4] Ibandronate US, Canada, UK, Western Europe, Eastern Europe BONE	Yes	Source: Industry; Role: NR	Yes
Coco M et al., 2003[5] Pamidronate US	Yes	Source: Not reported	Yes
Cosman F et al., 2001[6] Estrogen, PTH US	Yes	Source: Government; Role: NR	Yes
Cosman F et al., 2005[7] Alendronate, PTH US	No	Source: Government; Role: described	Yes
Fukunaga M et al., 2002[8] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH	No	Source: Industry; Role: NR	Yes

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 16-18: Standard, Funding, Relevance

Author, Year, Drug, Country, Trial name	Control group standard of care?	Funding	Relevance?
Garcia-Delgado I et al., 1997[9] Calcitonin, Etidronate Western Europe	Yes	Source: Government; Role: NR	No
Greenspan SL et al., 2003[10] Alendronate, Estrogen US	Yes	Source: Government; Role: described	Yes
Grotz W et al., 2001[11] Ibandronate Germany	No	Source: Not reported	Limited
Guanabens N et al., 2003[12] Alendronate, Etidronate Western Europe	Yes	Source: Government; Role: described	No
Harris ST et al., 2001[13] Estrogen, Resindronate US	Yes	Source: Industry; Role: NR	Yes
Hodsman AB et al., 1997[14] Calcitonin, Raloxifine Canada	No	Source: Government & Industry; Role: NR	Yes
Hosking D et al., 1998[15] Alendronate, Estrogen US, UK, Denmark	No	Source: Industry; Role: NR	Yes
Hosking D et al., 2003[16] Alendronate, Resindronate UK, Western Europe, Brazil	No	Source: Industry; Role: NR	Yes

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 16-18: Standard, Funding, Relevance

Author, Year, Drug, Country, Trial name	Control group standard of care?	Funding	Relevance?
Ishida Y et al., 2004[17] Calcitonin, Estrogen, Etidronate Japan YAMAGUCHI OP PREVENTION STUDY	No	Source: Not reported	Yes
Iwamoto J et al., 2003[18] Alendronate, Etidronate Japan	No	Source: Not reported	Yes
Iwamoto J et al., 2003[19] Alendronate, Etidronate Japan	No	Source: Not reported	Yes
Kananen K et al., 2005[20] Estrogen, Pamidronate, Testosterone Finland	Yes	Source: Hospital, Industry & Private; Role: NR	Limited
Kim SH et al., 2004[21] Pamidronate Asia	Yes	Source: Unclear; Role: NR	Limited
Kushida K et al., 2004[22] Etidronate, Resindronate Japan RESIDRONATE PHASE III RESEARCH III RESEARCH GROUP	Yes	Source: Industry & Private; Role: NR	Yes
Lindsay R et al., 1997[23] Estrogen, PTH US	No	Source: Government & Industry; Role: described	Yes
Lindsay R et al., 1999[24] Alendronate, Estrogen US	Yes	Source: Industry; Role: NR	Yes

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 16-18: Standard, Funding, Relevance

Author, Year, Drug, Country, Trial name	Control group standard of care?	Funding	Relevance?
Luckey M et al., 2004[25] Alendronate, Raloxifine US THE EFFECT STUDY	Yes	Source: Industry; Role: NR	Yes
Muscoso E et al., 2004[26] Alendronate, Raloxifine, Resindronate Italy	Yes	Source: Not reported	Yes
Ninkovic M et al., 2002[27] Pamidronate UK	No	Source: Not reported	Limited
Ravn P et al., 1996[28] Ibandronate Western Europe	Yes	Source: Not reported	Yes
Recker R et al., 2004[29] Ibandronate US, Western Europe	Yes	Source: Industry; Role: NR	Yes
Reid IR et al., 1994[30] Pamidronate Australia/NZ	No	Source: Government, Industry & Private; Role: NR	Yes
Reid IR et al., 2002[31] Zoledronic acid Western Europe, Australia	No	Source: Industry; Role: described	Yes
Reid IR et al., 2004[32] Estrogen, Raloxifine US, Canada, Western Europe, Australia/NZ, South Africa	No	Source: Industry; Role: NR	Yes

Appendix C.2 Quality Tables For Randomized Controlled Trials
Columns 16-18: Standard, Funding, Relevance

Author, Year, Drug, Country, Trial name	Control group standard of care?	Funding	Relevance?
Rosen CJ et al., 2005[33] Alendronate, Resindronate US FOSAMAX ACTONEL COMPARISON TRI	Yes	Source: Industry; Role: NR	Yes
Wimalawansa SJ, 1998[34] Estrogen, Etidronate UK	Yes	Source: Not reported	Yes

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Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(1) Aims	(2) Time period covered
Torgerson, 2001[1]	Determine if HRT reduced vertebral fractures	All trials until end of August 2001
Crannery, 2001[2]	Review the effect of etidronate on bone density & fractures in post menopausal women.	1966-1998
Wells, 2002[3]	Review the effects of HRT on bone density and fractures in postmenopausal women.	Articles from 1966 to 1999
Cranney, 2002[4]	Review the effects of risedronate on bone density & #'s in post menopausal women	Articles from 1966 to the end of 2000
Cranney, 2002[5]	Review the effect of alendronate on bone density and fractures in post menopausal women.	1980-1999
Cranney, 2002[6]	Review the effect of calcitonin on bone density and fractures in postmenopausal women	1966 to 2000
Karpf, 1997[7]	To evaluate the effect of treatment with alendronate sodium, on the incidence of nonvertebral fractures in postmenopausal women with osteoporosis	All completed prospective, randomized, placebo-controlled alendronate trails of at least two years duration
Papapoulos, 2004[8]	Assess consistency of the effect of alendronate in reducing the risk of hip fractures among different studies & populations.	All randomized clinical trials w/ alendronate
Cranney, 2000[9]	Review the efficacy of calcitonin (subcutaneous or nasal) for the treatment & prevention of corticosteroid induced osteoporosis	RCTs up to May 1998
Cranney, 2003[10]	Review efficiency of risedronate on bone density and fracture reduction in postmenopausal women.	Articles from 1990-2001
Cranney, 2001[11]	Review the efficacy of etidronate therapy in the prevention and treatment of postmenopausal osteoporosis	1966-1998
Farquhar, 2005[12]	To assess the effect of long-term hormone therapy on mortality, heart disease, venous thromboembolism, stroke, transient ischaemic attacks, breast cancer, colorectal cancer, ovarian cancer, endometrial cancer, gallbladder disease, cognitive function, deme	Trials up to 2004
Stevenson, 2005[13]	To establish the clinical effectiveness and cost-effectiveness of alendronate, etidronate, risedronate, raloxifine, or teriparatide for the prevention and treatment of osteoporosis and the prevention of osteoporotic fractures in postmenopausal women.	All trials up to 2002
Kanis, 1998[14]	To determine the effect of calcitonin on vertebral and other fractures	1988-1997
Shea, 2002[15]	To summarize controlled trials examining the effect of calcium on bone density and fractures in postmenopausal women	1966 - 2000
Papadimitropoulos, 2002[16]	To review the effect of vitamin D on bone density and fractures in postmenopausal women	1966 - 1999
Bischoff-Ferrari, 2005[17]	To estimate the effectiveness of vitamin D supplementation in preventing hip and nonvertebral fractures in older persons.	1960 - 2005

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(1) Aims	(2) Time period covered
Schachter, 2005[18]	To systematically assess, using a meta-analysis if appropriate, raloxifene's safety and efficacy to prevent osteoporotic vertebral fractures in postmenopausal women. To compare raloxifene against placebo and other drug treatments, including estrogen alone in women with hysterectomies, estrogen-progestin combination therapies, bisphosphonates (alendronate, risedronate and etidronate) and salmon calcitonin.	1966-2002
Avenell, 2005[19]	To determine the effects of vitamin D or analogues, with or without calcium, in the prevention of fractures in older people.	1966-2005

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(3) Eligibility criteria	(4) Number of patients	(5) Characteristics of identified articles: Study designs
Torgerson, 2001[1]	(1) RCT of HRT where women had been randomized to at least 12 mon. of HRT or to no HRT.	6,723	13 RCTs
Crannery, 2001[2]	(1) RCTs of at least 1yr duration comparing etidronate therapy with placebo or with calcium and/or vitamin D, 2)outcomes included fracture incidence or bone density and 3)participants were postmenopausal women	1,267	13 RCTs; all published and unpublished RCTs
Wells, 2002[3]	(1) RCT in postmenopausal women that compared an HRT intervention (estrogen used alone or estrogen opposed by progestin) with a placebo (2)HRT could be given in conjunction with a calcium and vitamin D, provided the other group received the same (3)results had to be reported with a follow up of at least one year on one or more of the outcomes of interest (4) both prevention and rx trials were accepted (rx referring to studies that included women w/ prevalent #'s at baseline)	9,958	57 RCTs
Cranney, 2002[4]	(1) Randomized, placebo-controlled trials of risedronate for osteoporosis in postmenopausal women defined as greater than 6 months postmenopausal); 2)follow up of at least one year; and 3)fracture incidence or bone mineral density data available	14,832	8 RCTs
Cranney, 2002[5]	(1) RCTs comparing postmenopausal women receiving alendronate to those not receiving alendronate with follow up of at least 1 year; and 2)fracture incidence, or bmd data	12,855	11 RCTs
Cranney, 2002[6]	(1) RCTs of at least 1-yr duration , comparing calcitonin therapy vs. placebo or calcium and/or vitamin D; 2)outcomes included bmd or fracture incidence; and 3)participants were postmenopausal women	3,993	30 RCTs
Karpf, 1997[7]	All postmenopausal women randomized to treatment with placebo or alendronate at a dose higher than 1mg per day for at least 2 year that evaluated the efficacy of treatment	1,602	5 RCTs
Papapoulos, 2004[8]	Aimed to included all RCT with alendronate in postmenopausal women with a t-score of 2.0 or less, or w/ a vertebral # in which there were sufficient data to evaluate the relative risk; specifically there was at least one patient in each treatment group that experienced a hip fracture	9,023	6 RCTs; one study listed as active-control rest were placebo control
Cranney, 2000[9]	RCT that used calcitonin for the prevention or treatment of steroid induced osteoporosis; men or women over age 18 with any underlying disease requiring therapy with steroids; randomized allocation of patients into treatment groups; adequate description of the intervention medications in terms of dosage scheduling and administration	441	9 RCTs
Cranney, 2003[10]	Randomized women to risedronate or an alternative (placebo or calcium and/or vit. D) and measured bmd for at least 1yr)	14,500	8 RCTs
Cranney, 2001[11]	Trials that randomized postmenopausal women to etidronate or an alternative (placebo or calcium and /or vitamin D) and measured bone density for at least 1 year	1,010	13 RCTs

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(3) Eligibility criteria	(4) Number of patients	(5) Characteristics of identified articles: Study designs
Farquhar, 2005[12]	Randomized double blind trials of hormone therapy (estrogens with or without progestogens) versus placebo, taken for at least one year by perimenopausal or postmenopausal women	35,089	15 RCTs
Stevenson, 2005[13]	• interventions- bisphosphonates: alendronate, etidronate and risedronate- serms:raloxifene- teriparatide [recombinant human pth (1-34)]• comparators- vitamin D- calcitriol (a vitamin 1 alph-hydroxylated derivative)- pharmacological doses of calcium- estrogens (opposed and unopposed)- exercise- placebo- no treatment• outcome measures: vertebral or non-vertebral fracture, associated effects, quality of life related to the study intervention, continuance and compliance.• study design: RCTs; trials were accepted as RCTs if the allocation of subjects to treatment groups was described by the authors as either randomized or double-blind.	Not tabulated	90 RCTs
Kanis, 1998[14]	Randomized trials that compared calcitonin therapy with placebo, no therapy, or calcium supplements with or without the use of vitamin D and that mentioned fracture as an outcome. A minimum study duration of 6 months was accepted. Languages accepted were English, German, Spanish, Italian, and French.	1,309	14 RCTs
Shea, 2002{#3207	Trials that randomized postmenopausal women to calcium supplementation or usual calcium intake in the diet and reported bone mineral density of the total body, vertebral spine, hip, or forearm, or recorded the number of fractures and followed patients for at least a year. Additionally the women were older than 45 years and absence of menses for a minimum of 6 months; treatment with doses of calcium at least 400mg/d	1,806	15 RCTs
Papadimitropoulos, 2002[16]	1).Participants were women older than 45 years with absence of menses for a minimum of 6 months;2).the treatment group received some form of vitamin D greater than 400iu daily, or some form of dihydroxyvitamin D;3).a follow up of at least 1 year;4).results reported on x-ray evidence of fractures of hip, vertebrae, or wrist, or bone mineral density measured in grams per centimeter, or grams per centimeter squared in at least one of the following sites: femoral neck, total hip, trochanter, lumbar spine, total body, and the combined forearm, and reporting results on individual patients(as opposed to number of fractures);5).the studies were RCTs	8,124	25 RCTs
Bischoff-Ferrari, 2005[17]	Only double blinded RCTs of oral vitamin D supplementation (cholecaciferol, ergocaciferol) with or without calcium supplementation vs calcium supplementation or placebo in older persons (grater than or equal to 60 years old) that examined hip or nonvertebral fractures were included. Trials with a minimum follow up of one year and required more than a total of 1 fracture in each trial	9,820	7 RCTs
Schachter, 2005[18]	Criteria: 1).an RCT involving the use of raloxifene of any dose compared to other drugs or placebo for postmenopausal women with low BMD (i.e., a T-score of more than 2.5 SD below the average value for peak young adult bone mass) or women with higher BMD levels (above the 2.5 SD threshold); 2).the inclusion of at least one of the following outcomes: incident radiographically confirmed vertebral fractures (primary outcome); BMD (secondary outcome), because of its key role in the clinical diagnosis of osteoporosis and despite its poor predictive value for future fractures; all reported adverse events (e.g., breast cancer, venous thromboembolic events, hot flashes)	11,931	17 RCTs

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(3) Eligibility criteria	(4) Number of patients	(5) Characteristics of identified articles: Study designs
Avenell, 2005[19]	Randomized or quasi-randomized trials comparing vitamin D or an analogue, alone or with calcium, against placebo, no intervention, or calcium, reporting fracture outcomes, in older people	18,935	38 RCTs

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(6) Characteristics of identified articles: Populations	(7) Characteristics of identified articles: Interventions
Torgerson, 2001[1]	Postmenopausal women	Estrogens (transdermal estradiol-.1mg,50ug; oral estradiol-1mg,2mg; oral conjugated estrogens-.625mg,.3mg)
Crannery, 2001[2]	Postmenopausal women	Intermittent cyclical method of administration of etidronate at 400mg per day for 14-20 days followed by 56-91 days of calcium and/or vitamin D; duration 1-3 years
Wells, 2002[3]	Postmenopausal women	HRT preparations (estrogen-progestin preparation were diverse) ;1-5 years duration
Cranney, 2002[4]	Postmenopausal women (defined as greater than 6 mon. post menopausal)	Risedronate 2.5mg; risedronate 5.0mg; duration 1-3 years
Cranney, 2002[5]	Postmenopausal women	Alendronate 1mg-40mg; duration 1-4yrs
Cranney, 2002[6]	Postmenopausal women	Calcitonin 40iu-400iu; salmon calcitonin; esl calcitonin; duration 1-5yrs; 1m, intranasal, suppository
Karpf, 1997[7]	Women with osteoporosis between ages of 42 & 85 years, postmenopausal at least four years, with lumbar spine bone mineral density at least 2.0 sd below the mean for young adult woman; all received 500mg of ca and were screened for vit d deficiency	Alendronate dose higher than 1mg per day for at least 2yrs;alendronate; 1mg, 2.5mg, 5mg, 10mg, 20/0mg, 20/5 mg, 40/0mg, 40/2.5mg; all received calcium 500mg and were screened for vitamin D deficiency
Papapoulos, 2004[8]	Postmenopausal women w/a t score of less than equal to 2.0, or w/a vertebral #	Alendronate 5-20mg/day; duration of studies 1-4.5years
Cranney, 2000[9]	Men or woman over age of 18, with any underlying disease that requires therapy with systematic steroids	Calcitonin; intranasal 100iu, 200iu, 400iu, 50iu, 100iu; control groups received placebo or were untreated; ca+vitd were accepted in control group if they were also given in equal doses to the treated group
Cranney, 2003[10]	Postmenopausal women 2 major groups of women included were those with mild bone less (prevention) or those with more severe bone less as defined by a tscore <-2.0 sd or prevalent verterleral facture (treatment)	Risedronate dosages included 2.5mg cyclical, 2.5 mg/d, 5mg cyclical, & 5mg/d for durations of at least one year
Cranney, 2001[11]	Postmenopausal women	Intermittent cyclic method of administration of etidronate at 400mg per day for 14-20 days followed by calcium and/or vitamin D

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(6) Characteristics of identified articles: Populations	(7) Characteristics of identified articles: Interventions
Farquhar, 2005[12]	Perimenopausal (women with spontaneous menopause who had menstruated irregularly within the last 12 months) and postmenopausal (surgical menopause or women with spontaneous menopause and amenorrhea for more than 12 months) women recruited from any healt	All estrogens with or without progestins, administered by oral, transdermal, subcutaneous, or intranasal routes; trials lasted 1 to 10 years
Stevenson, 2005[13]	Women with primary osteoporosis who were at least 6 months postmenopausal	Dosages: 1. alendronate-1-40 mg per day 2. etidronate- 200 and 400 mg per day 3. risedronate-2.5 and 5 mg per day 4. raloxifine-60 and 120 mg 5. teriparatide-20,25 and 40 ug per day duration: maximum total length of treatment with teriparatide should be 18 months; the length of treatment with the other interventions is not specified
Kanis, 1998[14]	Men and Women	Dosages: 1.calcitonin(i.m.)-100iu, 2.calcitonin(s.c.)-100iu, 3.calcitonin(nasal)-50iu,100iu,200iu,400iu; All but one study used synthetic salmon calcitonin, the exception used an intermittent regimen of human calcitonin(.25mg, given 4 times weekly for 4 weeks out of each 10 weeks); Duration - 6 months-3 years
Shea, 2002[15]	Women older than 45 years with absence of menses for a minimum of 6 months	Dosages: 1.calcium-500mg,831mg,1000mg 2.calcium citrate-1600mg,1000mg 3.calcium carbonate-500mg, 600mg, 800mg, 1000mg, 1200mg, 2000mg 4.calcium lactate gluconate-1000mg; Duration of trials 1-4 years
Papadimitropoulos, 2002[16]	Women older than 45 years with absence of menses for a minimum of 6 months	Dosages: 1.cholecalciferol-300iu,400iu,560iu,700iu,800iu,2000iu;2.alpha-Hydroxyvitamin D3-0.75ug;3.alpha-calcidiol-1ug,.5ug,1600iu;4.Alfarol-1ug;5.calcitriol-.5ug,.62ug,.43ug,1.0ug,;6.dihydroxycholecalciferol-0.5ug,0.25ug; Duration of trials: 1-5 years
Bischoff-Ferrari, 2005[17]	Because the target population consisted of older community-dwelling or institutionalized persons, the mean age of study participants had to be 60 years or older to be included	Dosages: cholecalciferol- 400iu/d, 700iu/d,800iu/d; Duration of trials: 12-60 months
Schachter, 2005[18]	Postmenopausal women	Dosages: raloxifene-60mg/d, 120mg/d; Duration - 2months-4years
Avenell, 2005[19]	Postmenopausal women or men over 65 years of age	Vitamin D or a vitamin D analogue in varying doses (examples:calcitriol, ergocalciferol, 1-alpha-hydrxy cholecalciferol,)

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(8) Main results	(9) Subgroups
Torgerson, 2001[1]	HRT use is associated with reduction in vertebral fractures, particularly among osteoporotic women	None
Crannery, 2001[2]	Beneficial effect of etidronate on reducing vertebral fractures with an associated increase in lumbar spine bone density; data suggested a reduction in vertebral fractures with a pooled relative risk of 0.63 (95%ci 0.44 to 0.92); there was no effect on nonvertebral fractures (relative risk 0.99,(95% ci 0.69 to 1.42).	None
Wells, 2002[3]	Data shows a nonsignificant trend toward a reduced incidence in vertebral and nonvertebral fractures; HRT has a consistent, favorable and large effect on bone density at all sites	
Cranney, 2002[4]	The 5mg daily dose of risedronate tended to show a larger impact on bone density than did the 2.5mg dose or cyclic administration ; longer duration of therapy produced larger effects; risedronate produces a substantial reduction of vertebral and nonvertebral fractures; the pooled relative risk for vertebral fractures in women given 2.5mg or more was 0.64(95% ci 0.54,0.77); the pooled rr of nonvertebral fractures in patients given 2.5mg or more was 0.73(95% ci 0.61,0.87)	
Cranney, 2002[5]	Alendronate increases bone density in both early post menopausal and those with established osteoporosis while reducing the rate of vertebral fracture over 2-3 years of treatment; the pooled relative risk for vertebral fractures in patients given 5mg or more of alendronate was 0.52(95%ci,0.43-0.65); the rr of nonvertebral fractures in patients given 10 mg or more was 0.51(95% ci 0.38-0.69)	
Cranney, 2002[6]	Calcitonin likely increases bone density in postmenopausal women predominantly at the lumbar spine and forearm for weekly doses greater than 250 iu, although the true effect may be smaller than the pooled estimate would suggest; calcitonin likely reduces the risk of vertebral fractures; its effect on nonvertebral fractures remains uncertain	
Karpf, 1997[7]	In postmenopausal women with osteoporosis, treatment with alendronate reduces the risk of nonvertebral fractures over at least 3 years; the estimated cumulative of nonvertebral fractures after 3 years was 12.6%in the placebo group and 9.0% in the alendronate group; the relative risk for nonvertebral fractures estimated using cox model was 0.71(95% ci, 0.502-0.997)(p=.048)	None

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(8) Main results	(9) Subgroups
Papapoulos, 2004[8]	Therapy with alendronate is associated with significant and clinically important reductions in the incidence of hip fractures in women with postmenopausal osteoporosis	In patients with a t-score of less than or equal to -2.0, or with a vertebral fracture, the effect of hip fracture risk consistently favored patients receiving alendronate therapy, with an overall reduction in risk of hip fracture of 45%(95% ci 16% to 64%, p=0.007); for patients who met the criteria of osteoporosis as defined by the who, the overall risk reduction was 55% (95% ci 29% to 72%, p=0.0008)"
Cranney, 2000[9]	Calcitonin has not yet demonstrated effectiveness at preventing fractures with steroid induced osteoporosis; calcitonin appears to prevent bone loss at the lumbar spine by about 3% in the first year; effect on bone density is greater in patients taking corticosteroids for more than 3 months; no consistent effect of different dosages; subcutaneous calcitonin showed greater prevention of bone loss (may be due to greater bioavailability of drug)	
Cranney, 2003[10]	There is good evidence for the efficacy of risedronate in the reduction of both vertebral and non vertebral fractures; risedronate is able to achieve this without increasing risk for overall withdrawals due to adverse effects	Vertebral fractures: 1.prevention population - the relative risk was 2.43(95% ci 0.12-49.43) 2.treatment population-estimate of rr using random effects model was 0.63(95% ci 0.52-0.77);p<0.01. nonvertebral fracture: 1.prevention population-rr was 0.48(95% ci 0.10-2.26) 2.treatment population -pooled estimate of rr was 0.73(95% ci 0.61-0.88);p<0.01
Cranney, 2001[11]	Data suggested a reduction in vertebral fractures with a pooled relative risk of 0.60%(95% ci 0.41-0.88); there was no effect on nonvertebral fractures; etidronate increases bone density at the lumbar spine and the femoral neck ; effects were larger at 4 years, though the numbers of patients followed was much smaller.	The treatment effect of etidronate was consistent across subgroups: prevention(rr:0.61) vs. treatment(rr:0.59)

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(8) Main results	(9) Subgroups
Farquhar, 2005[12]	Hormone therapy offered the benefit of a significant reduction in the risk of fracture (no greater in women at high risk of fractures) but only after 4 or 5 years of treatment	
Stevenson, 2005[13]	Of the five interventions, only raloxifene appeared to reduce the risk of vertebral fracture in postmenopausal women unselected for low bone mineral density (bmd). however, as the full data have not been made public, there is some uncertainty regarding this result. none of the five interventions has been shown to reduce the risk of non-vertebral fracture in women unselected for low bmd. all of the proposed interventions provided gains in qalys compared with no treatment in women with sufficient calcium and vitamin D intakes. the size of the qaly gain for each intervention was strongly related to the age of the patient. the estimated costs varied widely for the interventions. these net costs were markedly different by age, with some interventions becoming cost-saving at higher age ranges in patients with a prior fracture.	
Kanis, 1998[14]	Within the limitations of this study, treatment with calcitonin is associated with a significant decrease in the number of vertebral and non-vertebral fractures	None
Shea, 2002[15]	The relative risk of fractures of the vertebrae was 0.77, with a wide CI (95% CI 0.54-1.09); The relative risk for nonvertebral fracture was 0.86(95% CI 0.43-1.72). Calcium supplementation alone has a small positive effect on bone density. The data shows a trend toward reduction in vertebral fractures, but does not meaningfully address the possible effect of calcium on reducing the incidence of nonvertebral fractures.	None
Papadimitropoulos, 2002[16]	Vitamin D reduced the incidence of vertebral fractures (relative risk -0.63, 95% CI 0.45-0.88, P<0.01) and showed a trend toward reduced incidence of nonvertebral fractures (RR 0.77, 95% CI 0.57-1.04, P<0.01); Vitamin D decreases vertebral fractures and may decrease nonvertebral fractures; The available data are uninformative regarding the relative effects of standard and hydroxylated vitamin D.	None

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(8) Main results	(9) Subgroups
Bischoff-Ferrari, 2005[17]	A vitamin D dose of 700 to 800iu/d reduced the relative risk of hip fracture by 26%(pooled RR,0.74; 95% CI, 0.61-0.88) and any nonvertebral fracture by 23% pooled RR,0.77; 95% CI, 0.68-0.87) vs calcium or placebo. Oral vitamin D supplementation between 700 to 800 iu/d appears to reduce the risk of hip and any nonvertebral fractures in ambulatory or institutionalized elderly persons. An oral vitamin D dose of 400 iu/d is not sufficient for fracture prevention.	For hip fracture prevention, only 3 studies provided separate results by sex. The pooled RR was 0.73 (95% CI 0.61-0.89) for 3 studies involving 5,838 women, and the RR was 0.76 (95% CI 0.35-1.67) for the 1 study involving 2,037 men. For any nonvertebral fracture prevention only 4 studies provided separate results by sex. The pooled RR was 0.80 (95% CI 0.70-0.91) for studies involving 5,975 women, and the RR was 0.70 (95% CI 0.40-1.20) for the 1 study involving 2,037 men. When studies were sorted by length of treatment and follow up they were unable to discern a clear difference in the effect of vitamin D for both hip and any nonvertebral fractures.
Schachter, 2005[18]	Raloxifene has no effect on the incidence of nonvertebral fractures such as hip fractures. Compared with placebo, raloxifene's primary clinical benefit is a reduction in vertebral fracture in older postmenopausal women, particularly if some vertebral fractures are present at baseline. This benefit is offset by a similar increase in serious adverse events due to venous thromboembolic disease. Raloxifene causes significantly more mild to moderate adverse events such as hot flashes, and leg cramps compared with placebo, but significantly less vaginal bleeding than estrogen-progestin combination therapy. Because of trial diversity, the planned meta- analysis to compare raloxifene's efficacy with other drugs used to prevent osteoporosis could not be accomplished.	

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(8) Main results	(9) Subgroups
Avenell, 2005[19]	Vitamin D alone showed no statistically significant effect on hip fracture, vertebral fracture or any new fractures. Vitamin D with calcium marginally reduced hip fractures, non vertebral fractures, but there was no evidence of effect on vitamin D with calcium on vertebral fractures. The effect appeared to be restricted to those living in institutionalized care. There is no evidence of advantage of analogues of vitamin D compared with vitamin D.	In the subgroup analysis by history of prior fracture, there was no evidence of a statistically significant reduction in effect of calcium and vitamin D in hip fracture in populations selected on the basis of prior fracture. In subgroup analysis by residential status (institution versus community) there was a statistically significant reduction in hip fracture incidence in the institutional residents subgroup , but not in the community dwelling group

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(10) Adverse events	(11) Comments
Torgerson, 2001[1]	Not reported	
Crannery, 2001[2]	Not reported	
Wells, 2002[3]	Not reported	
Cranney, 2002[4]	Treatment had little or no impact on the risk of discontinuing medication (rr 0.94; 95% ci 0.80, 1.10); for discontinuation due to gastrointestinal side effects, the pooled rr was 0.97 (95% ci 0.90, 1.04);the pooled rr for dyspepsia and abdominal pain were similar; for esophagitis, the pooled rr from 5 trials was 0.91(95% ci 0.70,1.18)	The serious methodological limitation of these studies is the consistently very high loss to follow up
Cranney, 2002[5]	The relative risk for discontinuing alendronate (5mg or greater) due to adverse effects was 1.15(95% ci 0.93-1.42); the pooled rr for discontinuing medication due to gastrointestinal side effects for 5mg or grater was 1.03(0.81-1.30, p=0.83) and the pooled rr for gastrointestinal adverse effects with continuation of medication was 1.03(0.98-1.07) p=0.23	The major methodological limitation was the loss to follow up; another limitation is the length of follow up, 4years or less in all studies to date
Cranney, 2002[6]	According to the authors in general the trials were poor in their reporting of adverse events	Large loss to follow up, particularly in the proof trials
Karpf, 1997[7]	Not reported	A limitation was that nonvertebral fractures were self reported ; however, all fractures were confirmed by radiography or by physician examination, and self report has been shown to be accurate for most nonvertebral fracture; another possible criticism in the individual studies is that nonvertebral fractures were captured as safety end points, as opposed to efficacy end points
Papapoulos, 2004[8]	Not reported	Limitations: 1.primarily caucasian women only 2.not all studies can be classified as fracture studies and thus the question arises whether all the trials should be weighted equally
Cranney, 2000[9]	Flushing rashes & nausea- these were increased in calcitonin group relative to control group	All trials had small sample sizes (less than 40 per group);
Cranney, 2003[10]		
Cranney, 2001[11]	The pooled estimate showed no statistical difference between placebo and etidronate for the risk of withdrawal overall(rr:0.89, 95% ci:0.71-1.13), with consistency across studies; drop out due to side effects(rr:1.51(0.69 to 3.32), consistent across studies	

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(10) Adverse events	(11) Comments
Farquhar, 2005[12]	Studies included a range of adverse effects doubling or tripling of the risk of thromboembolic events, a large increase in endometrial cancer risk in women taking estrogen without progestogen, an increased incidence of gallbladder disease and a possible link between hormone therapy and breast cancer, significantly increased incidence of stroke; significantly increased risk of coronary events and venous thromboembolism, with the increased risk becoming evident during the first year of use	The authors state that hormone therapy should only be considered for the prevention of fractures if other treatments are contraindicated and if the cardiovascular risks are low (the benefits of hormone therapy will generally be outweighed by the ongoing and cumulative risk of cardiovascular disease or breast cancer)
Stevenson, 2005[13]	Allendronate : one third of alendronate users reported gastrointestinal adverse events etidronate :has been associated with gastrointestinal adverse events risedronate : overall distribution of adverse events and of adverse upper gastrointestinal events, was comparable in the intervention and placebo groups raloxifene : three fold increase risk of venous thromboembolism ; higher incidence of hot flashes; arthalgia, dizziness, leg cramps, influenza like syndrome, endometrial cavity fluid, peripheral edema, and worsening of diabetes are more common teriparatide : nausea, headache mild discomfort at injection site	
Kanis, 1998[14]	Not reported	The limitations to consider: 1.a large number of publications did not report the occurrence of fractures 2.several of the studies, although randomized, were open rather than double blind 3.the duration of the studies was relatively short and in only two exceed 2 years.
Shea, 2002[15]	Not reported	Large loss to follow up; unexplained heterogeneity of results across studies. The estimates provided by the analysis are limited by problems inherent in the original studies, including a lack of uniformity in outcome measures.
Papadimitropoulos, 2002[16]	Vitamin D resulted in an increased risk of discontinuing medication in comparison to control as a result of either symptomatic adverse events or abnormal laboratory results (RR 1.37, 95% CI 1.01-1.88), an effect that was similar in trials of standard and hydroxylated vitamin D. On most occasions, the adverse laboratory result was hypercalciuria.	Inferences from the results of these analyses are limited by the variability in study designs, methodological weaknesses in the primary studies, the paucity of data, and the inconsistency of results; the methods of supplementation, and the use of calcium in addition to vitamin D, vary from study to study; another major issue is the possibility that vitamin D will have a different impact in different populations; the variability in study results further limits any inference one can make on the basis of the studies to date.
Bischoff-Ferrari, 2005[17]	Not reported	All trials were performed in primarily white populations, so the meta-analysis cannot address vitamin D effects in other racial or ethnic groups
Schachter, 2005[18]	MORE trial showed increase in serious adverse events due to venous thrombo-embolic disease compared to placebo	The most important observed clinical outcomes were a reduction in symptomatic vertebral fractures, a reduction in early invasive breast cancer in postmenopausal women and an increase in thrombo-embolic events.

Appendix C.3 Systematic Reviews Data Evidence Table

Author, Year	(10) Adverse events	(11) Comments
Avenell, 2005[19]	Hypercalcemia was more common when vitamin D or its analogue was given compared with placebo or calcium. The risk was particularly high with calcitriol. There was no evidence that vitamin D increased gastro-intestinal symptoms or renal disease. The risk of death during the study appeared marginally lower in participants given vitamin D or its analogues than in those given placebo or calcium.	

Appendix C.3 Systematic Reviews Quality Assessment Evidence Table - Internal Validity

Author, Year	Comprehensive sources?	Literature search strategy specified?	Imoprtant studies missing?	Explicit eligibility criteria?	Adequate detail primary studi
Torgerson, 2001[1]	Yes	Yes	No	Yes	Yes
Cranney, 2001[2]	Yes	Yes	No	Yes	Yes
Wells, 2002[3]	Yes	Yes	No	Yes	Yes
Cranney, 2002[4]	Yes	Yes	No	Yes	Yes
Cranney, 2002[5]	Yes	Yes	No	Yes	Yes
Cranney, 2002[6]	Yes	Yes	No	Yes	Yes
Karpf, 1997[7]	Not reported	No	No	Yes	Yes
Papapoulos, 2004[8]	Yes	Yes	No	Yes	Yes
Cranney, 2000[9]	Yes	Yes	No	Yes	Yes
Cranney, 2003[10]	Yes	Yes	No	Yes	Yes
Cranney, 2001[11]	Yes	Yes	No	Yes	Yes
Farquhar, 2005[12]	Yes	Yes	No	Yes	Yes
Stevenson, 2005[13]	Yes	Yes	No	Yes	Yes
Kanis, 1998[14]	Yes	Yes	No	Yes	Yes
Shea, 2002[15]	Yes	Yes	No	Yes	Yes
Papdimitropoulos, 2002[16]	Yes	Yes	No	Yes	Yes
Bischoff-Ferrari, 2005[17]	Yes	Yes	No	Yes	Yes
Schachter, 2005[18]	Yes	Yes	No	Yes	Yes

Appendix C.3 Systematic Reviews Quality Assessment Evidence Table - External Validity

Author, Year	Study results synthesized?	(1) Exclusion criteria: All trials except:	(2) Relevant to a key question?
Cranney, 2000[9]	Yes	RCT that used calcitonin for the prevention or treatment of steroid induced osteoporosis; men or women over age 18 with any underlying disease requiring therapy with steroids; randomized allocation of patients into treatment groups; adequate description of the intervention medications in terms of dosage scheduling and administration	Yes
Cranney, 2001[2]	Yes	See wells, 2002 for eligibility criteria; additional exclusion criteria: * didn't include data from the HRT arm or combined HRT/etibronate arm of wimalawansa 1995 & 1998.	Yes
Cranney, 2001[11]	Yes	Trials that randomized postmenopausal women to etidronate or an alternative (placebo or calcium and /or vitamin D) and measured bone density for at least 1 year	Yes
Cranney, 2002[4]	Yes	(1) Randomized, placebo-controlled trials of risedronate for osteoporosis in postmenopausal women defined as greater than 6 months postmenopausal); 2)follow up of at least one year; and 3)fracture incidence or bone mineral density data available	Yes
Cranney, 2002[5]	Yes	(1) RCTs comparing postmenopausal women receiving alendronate to those not receiving alendronate with follow up of at least 1 year; and 2)fracture incidence, or bmd data	Yes
Cranney, 2002[6]	Yes	(1) RCTs of at least 1-yr duration , comparing calcitonin therapy vs. placebo or calcium and/or vitamin D; 2)outcomes included bmd or fracture incidence; and 3)participants were postmenopausal women	Yes
Cranney, 2003[10]	Yes	Randomized women to risedronate or an alternative (placebo or calcium and/or vit. D) and measured bmd for at least 1yr)	Yes
Farquahr, 2005[12]	Yes	Randomized double blind trials of hormone therapy (estrogens with or without progestogens) versus placebo, taken for at least one year by perimenopausal or postmenopausal women additional exclusion criteria: *studies with co interventions that might effect the outcomes being measured or which used topical vaginal hormone therapy creams, topical hormone therapy tablets, or hormone therapy rings	Yes
Karpf, 1997[7]	Yes	All postmenopausal women randomized to treatment with placebo or alendronate at a dose higher than 1mg per day for at least 2 year that evaluated the efficacy of treatment	Yes
Papapoulos, 2004[8]	Yes	Aimed to included all RCT with alendronate in postmenopausal women with a t-score of 2.0 or less, or w/ a vertebral # in which there were sufficient data to evaluate the relative risk; specifically there was at least one patient in each treatment group that experienced a hip fracture	Yes
Stevenson, 2005[13]	Yes	See #3 eligibility criteria on evidence table additional exclusion criteria: *studies were excluded if they included participants with secondary osteoporosis (e.g. related to therapy with corticosteroids), or drew their participants exclusively from patients with specific diseases known to effect fracture rates (e.g. parkinson's disease) *only published studies (including those only available in abstract form) were included *it was possible only to include studies published in english, French, German, Italian, or Spanish. this led to an exclusion of one possibly relevant study published only in Japanese	Yes

Appendix C.3 Systematic Reviews Quality Assessment Evidence Table - External Validity

Author, Year	Study results synthesized?	(1) Exclusion criteria: All trials except:	(2) Relevant to a key question?
Torgerson, 2001[1]	Yes	(1) RCT of HRT where women had been randomized to at least 12 mon. of HRT or to no HRT.	Yes
Wells, 2002[3]	Yes	(1) RCT in postmenopausal women that compared an HRT intervention (estrogen used alone or estrogen opposed by progestin) with a placebo (2)HRT could be given in conjunction with a calcium and vitamin D, provided the other group received the same (3)results had to be reported with a follow up of at least one year on one or more of the outcomes of interest (4) both prevention and rx trials were accepted (rx referring to studies that included women w/ prevalent #'s at baseline)	Yes
Kanis, 1998[14]		Randomized trials that compared calcitonin therapy with placebo, no therapy, or calcium supplements with or without the use of vitamin D and that mentioned fracture as an outcome. A minimum study duration of 6 months was accepted. Languages accepted were English, German, Spanish, Italian, and French.	Yes
Shea, 2002[15]	Yes	Trials that randomized postmenopausal women to calcium supplementation or usual calcium intake in the diet and reported bone mineral density of the total body, vertebral spine, hip, or forearm, or recorded the number of fractures and followed patients for at least a year. The women were older than 45years and absence of menses for a minimum of 6 months; treatment with doses of calcium at least 400mg/d	Yes
Papadimitropoulos, 2002[16]	Yes	1).Participants were women older than 45 years with absence of menses for a minimum of 6 months;2).the treatment group received some form of vitamin D greater than 400iu daily, or some form of dihydroxyvitamin D;3).a follow up of at least 1 year;4).results reported on x-ray evidence of fractures of hip, vertebrae, or wrist, or bone mineral density measured in grams per centimeter, or grams per centimeter squared in at least one of the following sites: femoral neck, total hip, trochanter, lumbar spine, total body, and the combined forearm, and reporting results on individual patients(as opposed to number of fractures);5).the studies were RCTs. Exclusion criteria: studies that compared different types or doses of vitamin D.	Yes
Bischoff-Ferrari, 2005[17]	Yes	Only double blinded RCTs of oral vitamin D supplementation (cholecaciferol, ergocaciferol) with or without calcium supplementation vs calcium supplementation or placebo in older persons (greater than or equal to 60 years old) that examined hip or nonvertebral fractures were included. Trials with a minimum follow up of one year and required more than a total of 1 fracture in each trial. Exclusion criteria: studies that focused on patients following organ transplantation or stroke, receiving steroid therapy or care for Parkinson disease, or unstable health states, such as after acute hospitalization; RCTs that used active vitamin D metabolites and intramuscular injections of vitamin D.	Yes
Schachter, 2005[18]	Yes	Inclusion criteria: 1).an RCT involving the use of raloxifene of any dose compared to other drugs or placebo for postmenopausal women with low BMD (i.e., a T-score of more than 2.5 SD below the average value for peak young adult bone mass) or women with higher BMD levels (above the 2.5 SD threshold); 2).the inclusion of at least one of the following outcomes: incident radiographically confirmed vertebral fractures (primary outcome); BMD (secondary outcome), because of its key role in the clinical diagnosis of osteoporosis and despite its poor predictive value for future fractures; all reported adverse events (e.g., breast cancer, venous thromboembolic events, hot flashes) . Exclusion criteria: studies whose focus was the impact of raloxifene on biochemical markers of bone turnover, bone remodeling kinetics or bone histomorphometry; quality of life; cardiovascular risk; cognitive function; and neuromuscular function.	Yes
Avenell, 2005[19]	Yes	Randomized or quasi-randomized trials comparing vitamin D or an analogue, alone or with calcium, against placebo, no intervention, or calcium, reporting fracture outcomes, in older people.	Yes

Appendix C.3 Systematic Reviews Quality Assessment Evidence Table - External Validity

Author, Year	Study results synthesized?	(1) Exclusion criteria: All trials except:	(2) Relevant to a key question?
Cranney, 2000[9]	Yes	RCT that used calcitonin for the prevention or treatment of steroid induced osteoporosis; men or women over age 18 with any underlying disease requiring therapy with steroids; randomized allocation of patients into treatment groups; adequate description of the intervention medications in terms of dosage scheduling and administration	Yes
Cranney, 2001[2]	Yes	See wells, 2002 for eligibility criteria; additional exclusion criteria: * didn't include data from the HRT arm or combined HRT/etibronate arm of wimalawansa 1995 & 1998.	Yes
Cranney, 2001[11]	Yes	Trials that randomized postmenopausal women to etidronate or an alternative (placebo or calcium and /or vitamin D) and measured bone density for at least 1 year	Yes
Cranney, 2002[4]	Yes	(1) Randomized, placebo-controlled trials of risedronate for osteoporosis in postmenopausal women defined as greater than 6 months postmenopausal); 2)follow up of at least one year; and 3)fracture incidence or bone mineral density data available	Yes
Cranney, 2002[5]	Yes	(1) RCTs comparing postmenopausal women receiving alendronate to those not receiving alendronate with follow up of at least 1 year; and 2)fracture incidence, or bmd data	Yes
Cranney, 2002[6]	Yes	(1) RCTs of at least 1-yr duration , comparing calcitonin therapy vs. placebo or calcium and/or vitamin D; 2)outcomes included bmd or fracture incidence; and 3)participants were postmenopausal women	Yes
Cranney, 2003[10]	Yes	Randomized women to risedronate or an alternative (placebo or calcium and/or vit. D) and measured bmd for at least 1yr)	Yes
Farquahr, 2005[12]	Yes	Randomized double blind trials of hormone therapy (estrogens with or without progestogens) versus placebo, taken for at least one year by perimenopausal or postmenopausal women additional exclusion criteria: *studies with co interventions that might effect the outcomes being measured or which used topical vaginal hormone therapy creams, topical hormone therapy tablets, or hormone therapy rings	Yes
Karpf, 1997[7]	Yes	All postmenopausal women randomized to treatment with placebo or alendronate at a dose higher than 1mg per day for at least 2 year that evaluated the efficacy of treatment	Yes
Papapoulos, 2004[8]	Yes	Aimed to included all RCT with alendronate in postmenopausal women with a t-score of 2.0 or less, or w/ a vertebral # in which there were sufficient data to evaluate the relative risk; specifically there was at least one patient in each treatment group that experienced a hip fracture	Yes

Appendix C.3 Systematic Reviews Quality Assessment Evidence Table - External Validity

Author, Year	Study results synthesized?	(1) Exclusion criteria: All trials except:	(2) Relevant to a key question?
Stevenson, 2005[13]	Yes	See #3 eligibility criteria on evidence table additional exclusion criteria: *studies were excluded if they included participants with secondary osteoporosis (e.g. related to therapy with corticosteroids), or drew their participants exclusively from patients with specific diseases known to effect fracture rates (e.g. parkinson's disease) *only published studies (including those only available in abstract form) were included *it was possible only to include studies published in english, French, German, Italian, or Spanish. this led to an exclusion of one possibly relevant study published only in Japanese	Yes
Torgerson, 2001[1]	Yes	(1) RCT of HRT where women had been randomized to at least 12 mon. of HRT or to no HRT.	Yes
Wells, 2002[3]	Yes	(1) RCT in postmenopausal women that compared an HRT intervention (estrogen used alone or estrogen opposed by progestin) with a placebo (2)HRT could be given in conjunction with a calcium and vitamin D, provided the other group received the same (3)results had to be reported with a follow up of at least one year on one or more of the outcomes of interest (4) both prevention and rx trials were accepted (rx referring to studies that included women w/ prevalent #'s at baseline)	Yes
Kanis, 1998[14]		Randomized trials that compared calcitonin therapy with placebo, no therapy, or calcium supplements with or without the use of vitamin D and that mentioned fracture as an outcome. A minimum study duration of 6 months was accepted. Languages accepted were English, German, Spanish, Italian, and French.	Yes
Shea, 2002[15]	Yes	Trials that randomized postmenopausal women to calcium supplementation or usual calcium intake in the diet and reported bone mineral density of the total body, vertebral spine, hip, or forearm, or recorded the number of fractures and followed patients for at least a year. The women were older than 45years and absence of menses for a minimum of 6 months; treatment with doses of calcium at least 400mg/d	Yes
Papadimitropoulos, 2002[16]	Yes	1).Participants were women older than 45 years with absence of menses for a minimum of 6 months;2).the treatment group received some form of vitamin D greater than 400iu daily, or some form of dihydroxyvitamin D;3).a follow up of at least 1 year;4).results reported on x-ray evidence of fractures of hip, vertebrae, or wrist, or bone mineral density measured in grams per centimeter, or grams per centimeter squared in at least one of the following sites: femoral neck, total hip, trochanter, lumbar spine, total body, and the combined forearm, and reporting results on individual patients(as opposed to number of fractures);5).the studies were RCTs. Exclusion criteria: studies that compared different types or doses of vitamin D.	Yes
Bischoff-Ferrari, 2005[17]	Yes	Only double blinded RCTs of oral vitamin D supplementation (cholecaciferol, ergocaciferol) with or without calcium supplementation vs calcium supplementation or placebo in older persons (greater than or equal to 60 years old) that examined hip or nonvertebral fractures were included. Trials with a minimum follow up of one year and required more than a total of 1 fracture in each trial. Exclusion criteria: studies that focused on patients following organ transplantation or stroke, receiving steroid therapy or care for Parkinson disease, or unstable health states, such as after acute hospitalization; RCTs that used active vitamin D metabolites and intramuscular injections of vitamin D.	Yes

Appendix C.3 Systematic Reviews Quality Assessment Evidence Table - External Validity

Author, Year	Study results synthesized?	(1) Exclusion criteria: All trials except:	(2) Relevant to a key question?
Schachter, 2005[18]	Yes	Inclusion criteria: 1).an RCT involving the use of raloxifene of any dose compared to other drugs or placebo for postmenopausal women with low BMD (i.e., a T-score of more than 2.5 SD below the average value for peak young adult bone mass) or women with higher BMD levels (above the 2.5 SD threshold); 2).the inclusion of at least one of the following outcomes: incident radiographically confirmed vertebral fractures (primary outcome); BMD (secondary outcome), because of its key role in the clinical diagnosis of osteoporosis and despite its poor predictive value for future fractures; all reported adverse events (e.g., breast cancer, venous thromboembolic events, hot flashes) . Exclusion criteria: studies whose focus was the impact of raloxifene on biochemical markers of bone turnover, bone remodeling kinetics or bone histomorphometry; quality of life; cardiovascular risk; cognitive function; and neuromuscular function.	Yes
Avenell, 2005[19]	Yes	Randomized or quasi-randomized trials comparing vitamin D or an analogue, alone or with calcium, against placebo, no intervention, or calcium, reporting fracture outcomes, in older people.	Yes

Appendix C.3 Systematic Reviews Quality Assessment Evidence Table - External Validity

Author, Year	(3) Funding source and role of funder
Cranney, 2000[9]	External sources of support-no courses of support supplied: Internal sources of support-Loeb research institute, clinical epidemiology unit Canada.
Cranney, 2001[2]	Not reported
Cranney, 2001[11]	Merck provided an unrestricted educational grant; Proctor & Gamble contributed a small unrestricted educational grant; Ottawa Health Research Institute- clinical epidemiology unit, Ottawa hospital, Ottawa, Ontario, Canada; University of Ottawa- Institute of Population Health Canada
Cranney, 2002[4]	Merck provided partial funding.
Cranney, 2002[5]	Work was supported in part thru educational grants from Merck, Inc.
Cranney, 2002[6]	Not reported
Cranney, 2003[10]	A.Cranney was supported by an arthritis society junior research scholar and A. Papaioannou is a Ministry of Health clinician scientist; Ottawa Health Research Institute, clinical epidemiology Canada, Queen's University, department of medicine, Canada
Farquahr, 2005[12]	External sources of support - no sources of support supplied; internal sources of support - University of Aukland, New Zealand
Karpf, 1997[7]	Published data & data on file at Merck research laboratories; this study was supported in part by Merck research laboratories
Papapoulos, 2004[8]	Not reported
Stevenson, 2005[13]	Commissioned and funded by health technology assessment program on behalf of NICE (National Institute for Health and Clinical Excellence), United Kingdom
Torgerson, 2001[1]	Review partly funded from an unrestricted educational grant from Wyeth pharmaceuticals
Wells, 2002[3]	Not reported
Kanis, 1998[14]	Funded in part by the NHS R&D Health Technology Assessment Programme
Shea, 2002[15]	This work was supported by grants from Merck and Proctor & Gamble
Papadimitropoulo,2002[16]	Not reported
Bischoff-Ferrari, 2005[17]	This study was supported by grants from the Medical Foundation (Charles H. Farnsworth Trust, US Trust Company, Trustee and the Charles A. King Trust, Fleet National Bank) and the James Knox Memorial Foundation
Schachter, 2005[18]	Funded by Health Canada.
Avenell, 2005[19]	External sources of support: Australian Institute of Health and Welfare, Chief Scientist Office, Scottish Executive Health Department, Health Research Council of New Zealand, Medical Research Council UK; Internal sources of support: HealthCare Otago Endowment Trust, Dunedin; Health Services Research Unit, University of Aberdeen UK; Hull York Medical school UK; Department of Health Sciences, University of York UK

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Rec #: 3002

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Rec #: 3158

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Rec #: 1940

REJECTED: No Outcome of Interest

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Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Breast abnormality other than CA	Alendr	Estrog	2	22	123	57	123	0.22	(0.11, 0.42)*
Breast abnormality other than CA	Alendr	Estrog	1	0	330	28	110	0	(0, 0.04)*
Breast abnormality other than CA	Alendr-PTH	Estrog	1	0	30	5	30	0	(0, 1.02)
Breast abnormality other than CA	Calcit	Estrog	1	0	66	1	66	0	(0, 39)
Breast abnormality other than CA	Calcit	Estrog	1	0	21	2	22	0	(0, 5.54)
Breast abnormality other than CA	Etidro	Estrog	2	0	80	11	96	0	(0, 0.65)*
Breast abnormality other than CA	Alendr	placebo	4	75	837	71	560	1.02	(0.65, 1.62)
Breast abnormality other than CA	Ralox	placebo	7	62	1776	38	833	0.76	(0.49, 1.2)
Breast abnormality other than CA	Risedr	placebo	1	95	263	114	261	0.73	(0.51, 1.05)
Cancer	Pamidr	Estrog-Vit D	1	2	50	0	49	Inf+	(0.18, Inf+)
Cancer	Alendr	Vit D	1	0	60	2	57	0	(0, 5.04)
Cancer	Alendr	placebo	1	31	815	17	407	0.91	(0.48, 1.77)
Cancer	Calcit	placebo	1	1	32	0	31	Inf+	(0.02, Inf+)
Cancer	Etidro	placebo	1	0	75	1	77	0	(0, 40)
Cancer	Ibandr	placebo	3	2	676	0	205	Inf+	(0.05, Inf+)
Cancer	PTH	placebo	4	26	1484	22	764	0.59	(0.32, 1.1)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Cancer	Pamidr	placebo	1	1	51	0	50	Inf+	(0.03, Inf+)
Cancer	Ralox	placebo	3	14	6175	8	2959	0.81	(0.31, 2.23)
Cancer	Risedr	placebo	2	31	850	18	438	0.87	(0.46, 1.67)
Cancer	Tamox	placebo	2	4	95	9	95	0.42	(0.09, 1.58)
Cancer	Testos	placebo	1	1	54	0	54	Inf+	(0.03, Inf+)
Cancer: Breast Cancer	Ibandr	placebo	1	1	150	0	30	Inf+	(0.01, Inf+)
Cancer: Breast Cancer	PTH	placebo	1	1	17	0	17	Inf+	(0.03, Inf+)
Cancer: Breast Cancer	Ralox	placebo	1	3	859	2	286	0.5	(0.06, 5.99)
Cancer: Breast Cancer	Tamox	placebo	2	4	95	9	95	0.42	(0.09, 1.58)
Cancer: Cancer NOS	Pamidr	Estrog-Vit D	1	2	50	0	49	Inf+	(0.18, Inf+)
Cancer: Cancer NOS	Alendr	Vit D	1	0	60	2	57	0	(0, 5.04)
Cancer: Cancer NOS	Alendr	placebo	1	31	815	17	407	0.91	(0.48, 1.77)
Cancer: Cancer NOS	Calcit	placebo	1	1	32	0	31	Inf+	(0.02, Inf+)
Cancer: Cancer NOS	Ibandr	placebo	2	1	526	0	175	Inf+	(0.01, Inf+)
Cancer: Cancer NOS	PTH	placebo	3	25	1467	22	747	0.56	(0.3, 1.05)
Cancer: Cancer NOS	Pamidr	placebo	1	1	51	0	50	Inf+	(0.03, Inf+)
Cancer: Cancer NOS	Ralox	placebo	2	11	5316	6	2673	0.93	(0.31, 3.05)
Cancer: Cancer NOS	Risedr	placebo	2	31	850	18	438	0.87	(0.46, 1.67)
Cancer: Cancer NOS	Testos	placebo	1	1	54	0	54	Inf+	(0.03, Inf+)
Cancer: Gyn Cancer	Etidro	placebo	1	0	75	1	77	0	(0, 40)
Cardiac Mild	Alendr	Alendr-PTH	2	5	71	13	111	0.61	(0.16, 1.94)
Cardiac Mild	Alendr	Calcit	1	3	118	0	123	Inf+	(0.43, Inf+)
Cardiac Mild	Alendr	PTH	1	2	28	1	27	1.98	(0.1, 122)
Cardiac Mild	Alendr	Ralox	1	10	83	8	82	1.27	(0.42, 3.91)
Cardiac Mild	Etidro	Calcium	1	1	37	0	17	Inf+	(0.01, Inf+)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Cardiac Mild	Alendr	Estrog	1	25	93	23	93	1.12	(0.55, 2.28)
Cardiac Mild	Etidro	Estrog	1	1	37	0	20	Inf+	(0.01, Inf+)
Cardiac Mild	Alendr	Vit D	1	0	60	1	57	0	(0, 37.1)
Cardiac Mild	Alendr	placebo	7	90	701	83	585	0.95	(0.67, 1.35)
Cardiac Mild	Alendr-Ralox	placebo	1	7	84	6	82	1.15	(0.31, 4.35)
Cardiac Mild	Calcit	placebo	1	0	123	2	58	0	(0, 2.49)
Cardiac Mild	Ibandr	placebo	4	515	2612	254	1188	0.98	(0.82, 1.16)
Cardiac Mild	PTH	placebo	1	1	8	0	8	Inf+	(0.03, Inf+)
Cardiac Mild	Ralox	placebo	6	249	6313	142	3117	0.91	(0.73, 1.14)
Cardiac Serious	Etidro	Risedr	1	1	117	3	118	0.33	(0.01, 4.2)
Cardiac Serious	Alendr	Alendr-PTH	1	1	30	1	30	1	(0.01, 81.2)
Cardiac Serious	Alendr	Calcit	1	0	140	1	75	0	(0, 20.9)
Cardiac Serious	Alendr	Estrog	2	3	123	1	123	3.03	(0.24, 161)
Cardiac Serious	Alendr	Estrog	1	99	997	15	110	0.7	(0.38, 1.35)
Cardiac Serious	Alendr-PTH	Estrog	1	1	30	1	30	1	(0.01, 81.2)
Cardiac Serious	Etidro	Estrog	1	1	17	0	18	Inf+	(0.03, Inf+)
Cardiac Serious	Alendr	placebo	5	171	2171	86	1205	1.01	(0.77, 1.35)
Cardiac Serious	Calcit	placebo	1	1	75	0	72	Inf+	(0.02, Inf+)
Cardiac Serious	Etidro	placebo	1	1	36	0	36	Inf+	(0.03, Inf+)
Cardiac Serious	Ibandr	placebo	2	131	2061	68	979	0.95	(0.69, 1.3)
Cardiac Serious	Ralox	placebo	4	466	5727	253	2927	0.92	(0.87, 1.09)
Cardiac Serious	Risedr	placebo	2	70	850	40	438	0.88	(0.58, 1.37)
Cardiac Serious: Cardiac death	Alendr	placebo	1	1	32	0	38	Inf+	(0.03, Inf+)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Cardiac Serious: Cardiac death	Ralox	placebo	1	53	5129	24	2576	1.11	(0.67, 1.89)
Dermatologic	Etidro	Risedr	2	11	391	9	391	1.23	(0.46, 3.39)
Dermatologic	Alendr	Alendr-PTH	2	0	71	12	111	0	(0, 0.47)*
Dermatologic	Alendr	PTH	1	0	28	5	27	0	(0, 0.97)*
Dermatologic	Calcit	Calcium	1	1	22	0	22	Inf+	(0.03, Inf+)
Dermatologic	Etidro	Calcium	1	1	25	0	11	Inf+	(0.01, Inf+)
Dermatologic	Alendr	Estrog	1	321	997	31	110	1.21	(0.77, 1.94)
Dermatologic	Alendr	Vit D	2	4	136	2	66	0.97	(0.18, 5.31)
Dermatologic	Alendr	placebo	6	360	1346	192	671	0.97	(0.78, 1.21)
Dermatologic	Calcit	placebo	6	36	245	9	216	4.22	(1.88, 10.5)*
Dermatologic	Etidro	placebo	1	1	51	0	51	Inf+	(0.03, Inf+)
Dermatologic	Ibandr	placebo	3	468	2462	242	1158	0.92	(0.77, 1.1)
Dermatologic	PTH	placebo	4	13	75	1	77	20.9	(2.75, 967)*
Dermatologic	Ralox	placebo	1	2	102	0	102	Inf+	(0.19, Inf+)
Dermatologic	Testos	placebo	2	33	50	12	52	7.35	(2.69, 22.1)*
Dermatologic: Inj/app site rxns	Alendr	Alendr-PTH	2	0	71	12	111	0	(0, 0.47)*
Dermatologic: Inj/app site rxns	Alendr	PTH	1	0	28	5	27	0	(0, 0.97)*
Dermatologic: Inj/app site rxns	Alendr	placebo	3	5	46	5	43	0.96	(0.19, 4.8)
Dermatologic: Inj/app site rxns	Calcit	placebo	1	3	24	0	21	Inf+	(0.37, Inf+)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Dermatologic: Inj/app site rxns	Ibandr	placebo	1	46	1911	1	949	23.4	(3.98, 944)*
Dermatologic: Inj/app site rxns	PTH	placebo	4	13	75	1	77	20.9	(2.75, 967)*
ENT	Alendr	Calcit	2	0	133	14	138	0	(0, 0.29)*
ENT	Calcit	Vit D	1	2	15	0	15	Inf+	(0.19, Inf+)
ENT	Calcit	placebo	6	30	430	13	282	2.06	(0.96, 4.68)
ENT	Ralox	placebo	1	17	102	20	102	0.82	(0.37, 1.78)
Endocrine	Ibandr	placebo	1	2	159	1	81	1.02	(0.05, 60.9)
GI mild	Alendr	Etidro	3	11	132	3	105	4.34	(1.06, 25.7)*
GI mild	Alendr	Pamidr	1	2	21	0	19	Inf+	(0.17, Inf+)
GI mild	Alendr	Risedr	2	201	739	191	755	1.1	(0.87, 1.4)
GI mild	Etidro	Risedr	2	132	391	126	391	1.07	(0.79, 1.46)
GI mild	Alendr	Alendr-PTH	3	25	101	41	141	0.58	(0.26, 1.24)
GI mild	Alendr	Calcit	4	55	413	12	273	3.5	(1.79, 7.4)*
GI mild	Alendr	PTH	1	17	28	18	27	0.78	(0.22, 2.67)
GI mild	Alendr	Ralox	3	170	552	188	556	0.87	(0.67, 1.14)
GI mild	Calcit	Etidro	1	0	66	1	66	0	(0, 39)
GI mild	Etidro	Calcium	6	57	222	30	198	2.14	(1.15, 4.05)*
GI mild	Alendr	Estrog	4	103	255	111	306	1.34	(0.9, 2)
GI mild	Alendr	Estrog	1	523	997	56	110	1.06	(0.7, 1.61)
GI mild	Alendr-PTH	Estrog	1	2	30	2	30	1	(0.07, 14.7)
GI mild	Etidro	Estrog	4	11	134	0	134	Inf+	(3.8, Inf+)*
GI mild	Ralox	Estrog	1	13	495	30	513	0.43	(0.21, 0.87)*
GI mild	Alendr	Vit D	11	218	834	20	66	1.26	(0.94, 1.67)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
GI mild	Etidro	Vit D	2	1	102	0	100	Inf+	(0.03, Inf+)
GI mild	Ibandr	Vit D	1	11	52	14	52	0.73	(0.26, 1.98)
GI mild	Alendr	placebo	57	11928	19927	8547	13903	1.02	(0.96, 1.09)
GI mild	Alendr-Ralox	placebo	1	5	84	5	82	0.97	(0.22, 4.42)
GI mild	Alendr-Vit D	placebo	1	3	30	8	30	0.31	(0.05, 1.5)
GI mild	Calcit	placebo	16	90	907	64	650	0.96	(0.65, 1.42)
GI mild	Etidro	placebo	17	1452	8841	2008	16815	1.44	(1.34, 1.55)*
GI mild	Ibandr	placebo	9	1762	5664	802	2522	1.02	(0.92, 1.13)
GI mild	PTH	placebo	3	133	777	49	669	2.65	(1.86, 3.85)*
GI mild	Pamidr	placebo	7	180	326	69	210	5.5	(2.97, 10.7)*
GI mild	Ralox	placebo	7	437	6779	212	3395	0.97	(0.81, 1.16)
GI mild	Risedr	placebo	18	6329	16650	3524	9211	0.99	(0.94, 1.05)
GI mild	Zoledr	placebo	2	35	347	11	110	1.34	(0.6, 3.21)
GI mild: Diarrhea	Alendr	Etidro	1	1	46	0	53	Inf+	(0.03, Inf+)
GI mild: Diarrhea	Alendr	Alendr-PTH	1	3	28	3	28	1	(0.12, 8.21)
GI mild: Diarrhea	Alendr	PTH	1	3	28	2	27	1.49	(0.16, 19.3)
GI mild: Diarrhea	Etidro	Calcium	3	19	108	8	79	2.01	(0.74, 5.87)
GI mild: Diarrhea	Etidro	Estrog	1	1	37	0	20	Inf+	(0.01, Inf+)
GI mild: Diarrhea	Alendr	Vit D	2	8	136	3	66	1.31	(0.39, 4.71)
GI mild: Diarrhea	Ibandr	Vit D	1	3	52	1	52	3.09	(0.24, 167)
GI mild: Diarrhea	Alendr	placebo	4	9	121	9	91	0.82	(0.25, 2.66)
GI mild: Diarrhea	Calcit	placebo	2	1	45	0	49	Inf+	(0.03, Inf+)
GI mild: Diarrhea	Etidro	placebo	5	7	213	18	219	0.38	(0.13, 0.98)*
GI mild: Diarrhea	Ibandr	placebo	1	17	159	1	81	9.52	(1.44, 405)*
GI mild: Diarrhea	Pamidr	placebo	1	16	81	10	41	0.76	(0.29, 2.12)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
GI mild: Diarrhea	Ralox	placebo	1	1	102	6	102	0.16	(0, 1.35)
GI mild: Diarrhea	Risedr	placebo	5	75	959	40	701	1.37	(0.9, 2.1)
GI mild: ↑ LFTs	Alendr	Alendr-PTH	1	2	43	1	83	3.95	(0.2, 239)
GI mild: ↑ LFTs	Alendr	placebo	1	1	146	0	95	Inf+	(0.02, Inf+)
GI mild: ↑ LFTs	Pamidr	placebo	1	1	51	2	50	0.48	(0.01, 9.57)
GI mild: Hepatobiliary	Calcit	placebo	1	2	168	0	83	Inf+	(0.09, Inf+)
GI mild: Hepatobiliary	Pamidr	placebo	1	0	51	1	50	0	(0, 38.2)
GI mild: Hepatobiliary	Ralox	placebo	1	260	5129	132	2576	0.99	(0.79, 1.24)
GI mild: Upper GI	Alendr	Etidro	3	7	132	1	105	7.55	(0.93, 350)
GI mild: Upper GI	Alendr	Pamidr	1	2	21	0	19	Inf+	(0.17, Inf+)
GI mild: Upper GI	Alendr	Risedr	2	201	739	190	755	1.11	(0.88, 1.41)
GI mild: Upper GI	Etidro	Risedr	2	34	391	36	391	0.94	(0.56, 1.58)
GI mild: Upper GI	Alendr	Alendr-PTH	1	6	28	9	28	0.58	(0.14, 2.23)
GI mild: Upper GI	Alendr	Calcit	4	46	413	9	273	3.42	(1.6, 8.16)*
GI mild: Upper GI	Alendr	PTH	1	6	28	7	27	0.78	(0.18, 3.25)
GI mild: Upper GI	Alendr	Ralox	2	154	469	178	474	0.82	(0.62, 1.08)
GI mild: Upper GI	Etidro	Calcium	4	20	160	11	170	2.08	(0.91, 5)
GI mild: Upper GI	Alendr	Estrog	3	84	225	86	276	1.44	(0.96, 2.18)
GI mild: Upper GI	Etidro	Estrog	2	9	31	0	48	Inf+	(3.33, Inf+)*
GI mild: Upper GI	Alendr	Vit D	8	73	479	11	66	1.16	(0.78, 1.73)
GI mild: Upper GI	Ibandr	Vit D	1	8	52	11	52	0.68	(0.21, 2.07)
GI mild: Upper GI	Alendr	placebo	42	9777	17922	7355	12588	0.97	(0.91, 1.03)
GI mild: Upper GI	Alendr-Vit D	placebo	1	3	30	8	30	0.31	(0.05, 1.5)
GI mild: Upper GI	Calcit	placebo	9	27	531	28	346	0.62	(0.34, 1.13)
GI mild: Upper GI	Etidro	placebo	13	590	8629	748	16596	1.5	(1.34, 1.68)*

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
GI mild: Upper GI	Ibandr	placebo	4	650	4515	302	2167	1.04	(0.88, 1.22)
GI mild: Upper GI	PTH	placebo	3	133	777	49	669	2.65	(1.86, 3.85)*
GI mild: Upper GI	Pamidr	placebo	6	111	286	20	190	8.03	(4.2, 16.1)*
GI mild: Upper GI	Ralox	placebo	2	72	886	27	303	1.01	(0.61, 1.71)
GI mild: Upper GI	Risedr	placebo	18	3769	16650	2130	9211	1.01	(0.95, 1.08)
GI mild: Upper GI	Zoledr	placebo	1	26	292	3	59	1.82	(0.53, 9.73)
GI mild: Upper GI: N/V	Etidro	Risedr	2	6	391	10	391	0.59	(0.18, 1.83)
GI mild: Upper GI: N/V	Alendr	Alendr-PTH	1	1	28	2	28	0.49	(0.01, 9.9)
GI mild: Upper GI: N/V	Alendr	Calcit	1	4	118	1	123	4.26	(0.41, 213)
GI mild: Upper GI: N/V	Alendr	PTH	1	1	28	1	27	0.96	(0.01, 78.5)
GI mild: Upper GI: N/V	Alendr	Ralox	1	13	223	12	233	1.14	(0.47, 2.8)
GI mild: Upper GI: N/V	Etidro	Calcium	3	19	141	11	150	1.97	(0.85, 4.78)
GI mild: Upper GI: N/V	Etidro	Estrog	2	9	31	0	48	Inf+	(3.33, Inf+)*
GI mild: Upper GI: N/V	Alendr	Vit D	4	29	225	2	66	1.35	(0.7, 2.64)
GI mild: Upper GI: N/V	Ibandr	Vit D	1	3	52	2	52	1.52	(0.17, 19)
GI mild: Upper GI: N/V	Alendr	placebo	16	819	7469	805	7180	0.97	(0.87, 1.08)
GI mild: Upper GI: N/V	Calcit	placebo	4	8	204	2	105	2.19	(0.42, 21.9)
GI mild: Upper GI: N/V	Etidro	placebo	9	39	498	32	494	1.26	(0.75, 2.13)
GI mild: Upper GI: N/V	Ibandr	placebo	3	188	2604	99	1218	0.92	(0.71, 1.2)
GI mild: Upper GI: N/V	PTH	placebo	3	133	777	49	669	2.65	(1.86, 3.85)*
GI mild: Upper GI: N/V	Pamidr	placebo	4	98	202	14	124	8.6	(4.3, 18.4)*
GI mild: Upper GI: N/V	Ralox	placebo	1	58	859	23	286	0.83	(0.49, 1.44)
GI mild: Upper GI: N/V	Risedr	placebo	5	68	776	41	480	1.04	(0.68, 1.61)
GI mild: Upper GI: N/V	Zoledr	placebo	1	26	292	3	59	1.82	(0.53, 9.73)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
GI mild: Upper GI:Rflx or esoph sx	Alendr	Etidro	1	1	70	0	36	Inf+	(0.01, Inf+)
GI mild: Upper GI:Rflx or esoph sx	Alendr	Risedr	1	10	219	7	222	1.47	(0.49, 4.64)
GI mild: Upper GI:Rflx or esoph sx	Alendr	Alendr-PTH	1	5	28	7	28	0.66	(0.14, 2.84)
GI mild: Upper GI:Rflx or esoph sx	Alendr	Calcit	1	3	118	0	123	Inf+	(0.43, Inf+)
GI mild: Upper GI:Rflx or esoph sx	Alendr	PTH	1	5	28	5	27	0.96	(0.19, 4.8)
GI mild: Upper GI:Rflx or esoph sx	Alendr	Ralox	1	6	223	4	233	1.58	(0.37, 7.73)
GI mild: Upper GI:Rflx or esoph sx	Alendr	Estrog	2	51	185	34	236	2.03	(1.15, 3.64)*
GI mild: Upper GI:Rflx or esoph sx	Alendr	Vit D	2	6	144	12	109	0.45	(0.13, 1.38)
GI mild: Upper GI:Rflx or esoph sx	Alendr	placebo	25	1689	15840	1248	11290	1.02	(0.94, 1.11)
GI mild: Upper GI:Rflx or esoph sx	Calcit	placebo	1	0	123	4	58	0	(0, 0.69)*
GI mild: Upper GI:Rflx or esoph sx	Ibandr	placebo	2	31	2445	11	1137	1.32	(0.64, 2.93)
GI mild: Upper GI:Rflx or esoph sx	Pamidr	placebo	3	12	165	3	107	2.47	(0.63, 14.1)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
GI mild: Upper GI:Rflx or esoph sx	Risedr	placebo	15	282	16344	181	9058	0.87	(0.72, 1.06)
Constitutional	Alendr	Alendr-PTH	2	0	73	5	113	0	(0, 2.08)
Constitutional	Alendr	Ralox	3	37	552	77	556	0.44	(0.29, 0.68)*
Constitutional	Etidro	Calcium	2	1	62	2	28	0.22	(0, 4.35)
Constitutional	Alendr	Estrog	2	6	123	9	123	0.65	(0.18, 2.13)
Constitutional	Alendr-PTH	Estrog	1	0	30	1	30	0	(0, 39)
Constitutional	Etidro	Estrog	1	1	37	0	20	Inf+	(0.01, Inf+)
Constitutional	Alendr	placebo	3	17	389	20	385	0.83	(0.4, 1.72)
Constitutional	Alendr-Ralox	placebo	1	0	84	2	82	0	(0, 5.19)
Constitutional	Calcit	placebo	8	24	311	0	200	Inf+	(3.7, Inf+)*
Constitutional	PTH	placebo	1	10	21	10	22	1.09	(0.28, 4.26)
Constitutional	Pamidr	placebo	4	23	91	22	75	Inf+	(0.13, Inf+)
Constitutional	Ralox	placebo	13	480	2478	185	1562	1.55	(1.27, 1.89)*
Constitutional	Risedr	placebo	1	0	35	1	31	0	(0, 34.5)
Constitutional	Tamox	placebo	2	18	48	7	48	3.71	(1.24, 12.4)*
Constitutional	Zoledr	placebo	2	92	347	46	110	4.28	(1.44, 17.4)*
Constitutional: Fever	Zoledr	placebo	1	39	292	2	59	4.38	(1.08, 38.5)*
Constitutional: Flushing	Calcit	placebo	6	10	250	0	168	Inf+	(1.67, Inf+)*
Constitutional: Flushing	Pamidr	placebo	1	12	21	17	22	0.4	(0.08, 1.74)
Constitutional: Flushing	Ralox	placebo	6	69	703	28	609	2.15	(1.34, 3.54)*
Constitutional: Flushing	Tamox	placebo	2	18	48	7	48	3.71	(1.24, 12.4)*
Constitutional: Flushing	Zoledr	placebo	1	32	55	26	51	1.33	(0.58, 3.09)
Constitutional: Hot Flashes	Ralox	placebo	6	410	1609	153	788	1.47	(1.18, 1.83)*
Constitutional: Weight Gain	Alendr	Estrog	1	6	93	8	93	0.73	(0.2, 2.53)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Constitutional: Weight Gain	Alendr	placebo	1	14	187	16	186	0.86	(0.38, 1.94)
Constitutional: Weight Gain	PTH	placebo	1	10	21	10	22	1.09	(0.28, 4.26)
Constitutional: Weight Gain	Pamidr	placebo	2	3	54	3	38	0.92	(0.11, 7.62)
Genitourinary	Alendr	Alendr-PTH	1	7	28	6	28	1.22	(0.29, 5.19)
Genitourinary	Alendr	PTH	1	7	28	6	27	1.16	(0.28, 4.98)
Genitourinary	Alendr	Estrog	2	345	1327	140	220	0.13	(0.09, 0.18)*
Genitourinary	Alendr	Vit D	4	5	272	6	66	0.31	(0.09, 0.92)*
Genitourinary	Alendr	placebo	5	377	1525	190	900	1.05	(0.85, 1.31)
Genitourinary	Calcit	placebo	1	0	10	1	10	0	(0, 39)
Genitourinary	Etidro	placebo	1	0	10	1	10	0	(0, 39)
Genitourinary	Ibandr	placebo	3	400	2462	185	1158	1.05	(0.86, 1.28)
Genitourinary	PTH	placebo	2	4	215	7	117	0.29	(0.06, 1.19)
Genitourinary	Ralox	placebo	4	9	623	7	376	1.05	(0.33, 3.53)
Genitourinary	Risedr	placebo	1	1	35	0	31	Inf+	(0.02, Inf+)
Genitourinary	Testos	placebo	2	19	88	13	87	1.61	(0.68, 3.92)
Genitourinary	Zoledr	placebo	1	36	55	30	51	1.32	(0.56, 3.14)
Genitourinary: Nephrolithiasis	Alendr	Vit D	4	5	272	6	66	0.31	(0.09, 0.92)*
Genitourinary: Nephrolithiasis	Alendr	placebo	1	1	24	0	24	Inf+	(0.03, Inf+)
Genitourinary: Nephrolithiasis	Calcit	placebo	1	0	10	1	10	0	(0, 39)
Genitourinary: Nephrolithiasis	Etidro	placebo	1	0	10	1	10	0	(0, 39)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Genitourinary: Nephrolithiasis	PTH	placebo	2	4	215	7	117	0.29	(0.06, 1.19)
Genitourinary: Prostate	Ralox	placebo	1	2	25	3	25	0.64	(0.05, 6.19)
Genitourinary: Prostate	Testos	placebo	2	17	88	12	87	1.53	(0.62, 3.83)
Gynecologic	Alendr	Estrog	2	9	133	48	133	0.1	(0.04, 0.24)*
Gynecologic	Alendr	Estrog	1	0	330	110	110	0	(0, 0)*
Gynecologic	Etidro	Estrog	2	0	51	16	50	0	(0, 0.32)*
Gynecologic	Ralox	Estrog	1	1	495	4	513	0.26	(0.01, 2.62)
Gynecologic	Alendr	placebo	4	59	587	60	508	0.96	(0.58, 1.57)
Gynecologic	Ralox	placebo	6	87	6475	35	3198	1.05	(0.69, 1.63)
Gynecologic	Risedr	placebo	1	23	263	35	261	0.62	(0.34, 1.12)
Hematologic	Alendr	Ralox	1	0	223	1	233	0	(0, 40.8)
Hematologic	Alendr	Estrog	1	1	93	2	93	0.5	(0.01, 9.69)
Hematologic	Calcit	Estrog	1	0	66	2	66	0	(0, 5.31)
Hematologic	Etidro	Estrog	1	0	66	2	66	0	(0, 5.31)
Hematologic	Alendr	placebo	1	1	187	2	186	0.5	(0.01, 9.56)
Hematologic	Calcit	placebo	2	0	234	2	149	0	(0, 2.62)
Hematologic	Ibandr	placebo	3	153	2462	66	1158	1.13	(0.83, 1.54)
Hematologic	Pamidr	placebo	2	19	37	20	40	0.95	(0.06, 14.4)
Hematologic	Ralox	placebo	9	185	6800	45	3528	2.11	(1.51, 3.01)*
Hematologic	Risedr	placebo	1	0	250	2	250	0	(0, 5.32)
Hematologic	Testos	placebo	1	15	54	0	54	Inf+	(4.54, Inf+)*
Hematologic: Thromboembolic events	Alendr	Ralox	1	0	223	1	233	0	(0, 40.8)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Hematologic: Thromboembolic events	Alendr	Estrog	1	1	93	2	93	0.5	(0.01, 9.69)
Hematologic: Thromboembolic events	Alendr	placebo	1	1	187	2	186	0.5	(0.01, 9.56)
Hematologic: Thromboembolic events	Ralox	placebo	9	185	6800	45	3528	2.11	(1.51, 3.01)*
Hypertension	Alendr	Estrog	1	5	93	6	93	0.82	(0.19, 3.38)
Hypertension	Alendr	placebo	1	7	187	9	186	0.77	(0.24, 2.36)
Hypertension	Ibandr	placebo	1	0	1911	1	949	0	(0, 19.4)
Hypertension	Ralox	placebo	2	2	289	5	199	0.35	(0.03, 2.23)
Hypertension	Risedr	placebo	1	7	263	15	261	0.45	(0.15, 1.19)
Immunologic	Alendr	PTH	1	0	73	3	73	0	(0, 2.4)
Immunologic	Alendr	Vit D	2	42	134	45	132	0.88	(0.44, 1.75)
Immunologic	Etidro	placebo	1	0	18	1	19	0	(0, 41.2)
Immunologic	PTH	placebo	1	59	1093	1	544	31	(5.31, 1247)*
Immunologic	Pamidr	placebo	1	8	9	7	8	1.13	(0.01, 101)
Immunologic	Zoledr	placebo	1	3	10	3	10	1	(0.1, 10.3)
Immunologic: Anaphylaxis	Etidro	placebo	1	0	18	1	19	0	(0, 41.2)
Immunologic: Graft Rejection	Alendr	Vit D	2	42	134	45	132	0.88	(0.44, 1.75)
Immunologic: Graft Rejection	Pamidr	placebo	1	8	9	7	8	1.13	(0.01, 101)
Immunologic: Graft Rejection	Zoledr	placebo	1	3	10	3	10	1	(0.1, 10.3)
Infection	Alendr	Alendr-PTH	1	0	30	1	30	0	(0, 39)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Infection	Alendr-PTH	Estrog	1	1	30	0	30	Inf+	(0.03, Inf+)
Infection	Alendr	Vit D	1	24	74	19	75	1.41	(0.65, 3.08)
Infection	Alendr	placebo	1	65	318	27	159	1.26	(0.75, 2.15)
Infection	Etidro	placebo	4	64	203	68	204	0.93	(0.6, 1.46)
Infection	Ibandr	placebo	1	2	150	1	30	0.39	(0.02, 23.9)
Infection	PTH	placebo	1	1	27	0	25	Inf+	(0.02, Inf+)
Infection	Ralox	placebo	1	6	102	6	102	1	(0.26, 3.89)
Infection	Testos	placebo	1	0	54	1	54	0	(0, 39)
Infection	Zoledr	placebo	1	26	292	4	59	1.34	(0.44, 5.51)
Metabolic	Alendr	Etidro	1	0	46	1	53	0	(0, 44.9)
Metabolic	Alendr	Alendr-PTH	1	3	43	23	83	0.2	(0.04, 0.72)*
Metabolic	Alendr	Calcit	1	3	15	2	15	1.6	(0.15, 22.3)
Metabolic	Alendr	PTH	2	2	174	31	175	0.04	(0, 0.18)*
Metabolic	Calcit	Etidro	1	10	10	10	10	NC	NC
Metabolic	Etidro	Calcium	3	3	132	3	116	0.77	(0.1, 6.23)
Metabolic	Pamidr	calcium	1	1	14	1	13	0.93	(0.01, 78.4)
Metabolic	Etidro	Estrog	2	3	51	0	50	Inf+	(0.96, Inf+)
Metabolic	Alendr	Vit D	7	25	425	10	66	0.24	(0.14, 0.4)*
Metabolic	Calcit	Vit D	2	2	64	0	65	Inf+	(0.19, Inf+)
Metabolic	Ibandr	Vit D	1	1	52	4	52	0.24	(0, 2.52)
Metabolic	Alendr	placebo	1	6	192	0	192	Inf+	(1.19, Inf+)*
Metabolic	Calcit	placebo	3	18	139	18	146	1.23	(0.34, 4.5)
Metabolic	Etidro	placebo	2	10	179	11	190	0	(0, 37.7)
Metabolic	Ibandr	placebo	3	339	2462	154	1158	1.1	(0.89, 1.36)
Metabolic	PTH	placebo	6	282	1377	20	727	9.17	(5.74, 15.4)*

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Metabolic	Pamidr	placebo	2	4	41	0	43	Inf+	(0.75, Inf+)
Metabolic: Hypercalcemia	Alendr	Alendr-PTH	1	0	43	2	83	0	(0, 10.3)
Metabolic: Hypercalcemia	Alendr	Calcit	1	3	15	2	15	1.6	(0.15, 22.3)
Metabolic: Hypercalcemia	Alendr	PTH	2	2	174	31	175	0.04	(0, 0.18)*
Metabolic: Hypercalcemia	Calcit	Etidro	1	5	10	4	10	1.47	(0.19, 12.4)
Metabolic: Hypercalcemia	Etidro	Calcium	2	0	118	3	102	0	(0, 1.4)
Metabolic: Hypercalcemia	Alendr	Vit D	3	4	153	14	221	0.37	(0.09, 1.22)
Metabolic: Hypercalcemia	Calcit	Vit D	2	2	64	0	65	Inf+	(0.19, Inf+)
Metabolic: Hypercalcemia	Alendr	placebo	1	6	192	0	192	Inf+	(1.19, Inf+)*
Metabolic: Hypercalcemia	Calcit	placebo	3	13	139	12	146	1.3	(0.45, 3.76)
Metabolic: Hypercalcemia	Etidro	placebo	2	4	179	5	190	0.71	(0.1, 4.78)
Metabolic: Hypercalcemia	PTH	placebo	5	278	1179	17	627	10.7	(6.48, 18.9)*
Metabolic: Hypercalcemia	Pamidr	placebo	2	1	41	0	43	Inf+	(0.03, Inf+)
Metabolic: Hypercalciuria	Alendr	Alendr-PTH	1	3	43	21	83	0.22	(0.04, 0.82)*
Metabolic: Hypercalciuria	Calcit	Etidro	1	7	10	9	10	0.28	(0, 4.35)
Metabolic: Hypercalciuria	Pamidr	calcium	1	1	14	1	13	0.93	(0.01, 78.4)
Metabolic: Hypercalciuria	Alendr	Vit D	5	17	346	10	66	0.26	(0.14, 0.46)*
Metabolic: Hypercalciuria	Calcit	placebo	1	7	10	10	10	0	(0, 2.26)
Metabolic: Hypercalciuria	Etidro	placebo	1	9	10	10	10	0	(0, 39)
Metabolic: Hypercalciuria	PTH	placebo	1	1	28	1	23	0.82	(0.01, 66.8)
Musculoskeletal	Etidro	Risedr	1	8	274	4	273	2.02	(0.53, 9.28)
Musculoskeletal	Alendr	Alendr-PTH	3	28	101	42	141	0.32	(0.08, 1.03)
Musculoskeletal	Alendr	PTH	4	126	275	103	275	1.65	(1.07, 2.57)*
Musculoskeletal	Etidro	Calcium	1	2	25	0	11	Inf+	(0.08, Inf+)
Musculoskeletal	Alendr	Estrog	1	2	30	0	30	Inf+	(0.19, Inf+)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Musculoskeletal	Alendr	Estrog	1	627	997	62	110	1.31	(0.86, 1.99)
Musculoskeletal	Alendr	Vit D	2	10	136	4	66	1.23	(0.42, 3.7)
Musculoskeletal	Ibandr	Vit D	1	6	52	4	52	1.56	(0.34, 8.01)
Musculoskeletal	Alendr	placebo	9	799	2040	410	1192	1.15	(0.95, 1.38)
Musculoskeletal	Calcit	placebo	2	1	48	2	46	0.48	(0.01, 9.28)
Musculoskeletal	Etidro	placebo	6	61	267	59	266	1.07	(0.69, 1.66)
Musculoskeletal	Ibandr	placebo	5	1304	2968	578	1327	1.16	(1, 1.34)
Musculoskeletal	PTH	placebo	2	17	558	5	561	3.49	(1.22, 12.2)*
Musculoskeletal	Pamidr	placebo	3	37	112	18	75	1.36	(0.64, 2.93)
Musculoskeletal	Ralox	placebo	8	124	1894	52	963	1.53	(1.04, 2.27)*
Musculoskeletal	Risedr	placebo	3	223	690	102	346	1.15	(0.86, 1.55)
Musculoskeletal	Zoledr	placebo	2	112	347	24	110	2.12	(1.21, 3.85)*
Musculoskeletal: Arthritis and Arthralgias	Alendr	Alendr-PTH	1	9	28	12	28	0.64	(0.18, 2.14)
Musculoskeletal: Arthritis and Arthralgias	Alendr	PTH	1	9	28	15	27	0.39	(0.11, 1.29)
Musculoskeletal: Arthritis and Arthralgias	Etidro	Calcium	1	1	25	0	11	Inf+	(0.01, Inf+)
Musculoskeletal: Arthritis and Arthralgias	Alendr	placebo	1	12	28	15	27	0.61	(0.18, 1.98)
Musculoskeletal: Arthritis and Arthralgias	Calcit	placebo	2	1	48	1	46	0.95	(0.01, 74.8)
Musculoskeletal: Arthritis and Arthralgias	Etidro	placebo	2	22	150	20	154	1.15	(0.57, 2.34)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Musculoskeletal: Arthritis and Arthralgias	Risedr	placebo	2	87	539	40	269	1.1	(0.72, 1.7)
Musculoskeletal: Arthritis and Arthralgias	Zoledr	placebo	2	58	347	16	110	1.27	(0.66, 2.57)
Musculoskeletal: Myalgias, cramps and limb pain	Alendr	Alendr-PTH	2	9	58	8	58	1.16	(0.34, 4.05)
Musculoskeletal: Myalgias, cramps and limb pain	Alendr	PTH	3	7	174	19	173	0.31	(0.1, 0.82)*
Musculoskeletal: Myalgias, cramps and limb pain	Etidro	Calcium	1	1	25	0	11	Inf+	(0.01, Inf+)
Musculoskeletal: Myalgias, cramps and limb pain	Alendr	Estrog	1	2	30	0	30	Inf+	(0.19, Inf+)
Musculoskeletal: Myalgias, cramps and limb pain	Alendr	Vit D	2	6	136	3	66	0.97	(0.25, 3.72)
Musculoskeletal: Myalgias, cramps and limb pain	Ibandr	Vit D	1	6	52	4	52	1.56	(0.34, 8.01)
Musculoskeletal: Myalgias, cramps and limb pain	Alendr	placebo	2	11	63	7	62	1.71	(0.52, 6.01)
Musculoskeletal: Myalgias, cramps and limb pain	Ibandr	placebo	2	191	2382	39	1105	2.24	(1.57, 3.29)*
Musculoskeletal: Myalgias, cramps and limb pain	PTH	placebo	1	16	541	5	544	3.28	(1.14, 11.5)*
Musculoskeletal: Myalgias, cramps and limb pain	Ralox	placebo	6	121	1584	42	802	1.99	(1.31, 3.09)*

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Musculoskeletal: Myalgias, cramps and limb pain	Zoledr	placebo	2	48	347	5	110	3.52	(1.31, 12)*
Neurologic, Mild	Etidro	Risedr	2	14	391	13	391	1.08	(0.46, 2.53)
Neurologic, Mild	Alendr	Alendr-PTH	1	4	28	8	28	0.42	(0.08, 1.87)
Neurologic, Mild	Alendr	PTH	1	4	28	6	27	0.59	(0.11, 2.88)
Neurologic, Mild	Etidro	Calcium	2	5	118	1	102	3.76	(0.39, 185)
Neurologic, Mild	Alendr	Estrog	1	52	93	44	93	1.41	(0.76, 2.62)
Neurologic, Mild	Etidro	Estrog	1	3	37	0	20	Inf+	(0.22, Inf+)
Neurologic, Mild	Alendr	placebo	5	173	714	124	502	1.32	(0.97, 1.8)
Neurologic, Mild	Calcit	placebo	6	18	243	2	184	10.8	(2.41, 101)*
Neurologic, Mild	Etidro	placebo	2	3	220	1	231	3.24	(0.26, 171)
Neurologic, Mild	Ibandr	placebo	3	581	2462	289	1158	0.95	(0.81, 1.13)
Neurologic, Mild	PTH	placebo	2	136	1192	77	544	0.76	(0.55, 1.04)
Neurologic, Mild	Pamidr	placebo	1	18	81	5	41	2.05	(0.66, 7.66)
Neurologic, Mild	Ralox	placebo	1	3	27	3	17	0.59	(0.07, 5.03)
Neurologic, Mild	Risedr	placebo	2	61	200	48	190	1.35	(0.83, 2.2)
Neurologic, Mild	Zoledr	placebo	1	7	55	0	51	Inf+	(1.43, Inf+)*
Neurologic, Mild: Headaches	Alendr	Alendr-PTH	1	3	28	6	28	0.45	(0.06, 2.39)
Neurologic, Mild: Headaches	Alendr	PTH	1	3	28	4	27	0.69	(0.09, 4.59)
Neurologic, Mild: Headaches	Etidro	Calcium	2	5	118	1	102	3.76	(0.39, 185)
Neurologic, Mild: Headaches	Etidro	Estrog	1	3	37	0	20	Inf+	(0.22, Inf+)
Neurologic, Mild: Headaches	Alendr	placebo	2	32	346	14	186	1.38	(0.68, 2.91)
Neurologic, Mild: Headaches	Calcit	placebo	3	8	107	1	99	8.37	(1.08, 380)*
Neurologic, Mild: Headaches	Etidro	placebo	2	3	220	1	231	3.24	(0.26, 171)
Neurologic, Mild: Headaches	PTH	placebo	2	87	651	44	544	1.7	(1.13, 2.59)*

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Neurologic, Mild: Headaches	Pamidr	placebo	1	18	81	5	41	2.05	(0.66, 7.66)
Neurologic, Mild: Headaches	Risedr	placebo	2	29	200	22	190	1.32	(0.7, 2.54)
Neurologic, Serious	Alendr	placebo	2	1	53	1	52	0.98	(0.01, 77.3)
Neurologic, Serious	Ibandr	placebo	2	32	2061	23	979	0.68	(0.38, 1.22)
Neurologic, Serious	Ralox	placebo	3	154	5418	84	2775	0.92	(0.7, 1.23)
Neurologic, Serious	Testos	placebo	1	1	46	0	24	Inf+	(0.01, Inf+)
Neurologic, Serious: Cerebrovascular events	Ibandr	placebo	2	1	2061	1	979	0.32	(0, 27.3)
Neurologic, Serious: Cerebrovascular events	Ralox	placebo	2	154	5231	83	2678	0.94	(0.71, 1.24)
Neurologic, Serious: Cerebrovascular events	Testos	placebo	1	1	46	0	24	Inf+	(0.01, Inf+)
Psychiatric	Alendr	Alendr-PTH	1	1	28	2	28	0.49	(0.01, 9.9)
Psychiatric	Alendr	PTH	1	1	28	2	27	0.47	(0.01, 9.54)
Psychiatric	Alendr	Estrog	1	312	997	36	110	0.94	(0.61, 1.47)
Psychiatric	Alendr	placebo	2	314	1025	158	529	1.01	(0.8, 1.28)
Psychiatric	PTH	placebo	1	8	21	9	22	0.89	(0.22, 3.57)
Psychiatric	Tamox	placebo	1	2	70	0	70	Inf+	(0.19, Inf+)
Renal Adverse Events	Alendr	Vit D	1	21	74	30	75	0.6	(0.28, 1.24)
Respiratory	Alendr	Alendr-PTH	1	2	28	3	28	0.65	(0.05, 6.14)
Respiratory	Alendr	PTH	1	2	28	1	27	1.98	(0.1, 122)
Respiratory	Alendr	Estrog	1	744	997	78	110	1.21	(0.75, 1.89)
Respiratory	Alendr	placebo	4	813	1203	436	662	0.88	(0.69, 1.1)
Respiratory	Ibandr	placebo	3	1189	2462	577	1158	0.98	(0.85, 1.13)
Respiratory	PTH	placebo	1	0	8	1	8	0	(0, 39)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Respiratory	Testos	placebo	2	2	100	1	78	1.64	(0.08, 101)
Serious Adverse Event NOS/Death	Alendr	Risedr	1	45	520	41	533	1.14	(0.71, 1.82)
Serious Adverse Event NOS/Death	Alendr	Calcit	2	10	258	8	198	1.05	(0.36, 3.18)
Serious Adverse Event NOS/Death	Alendr	PTH	1	0	73	1	73	0	(0, 39)
Serious Adverse Event NOS/Death	Alendr	Ralox	2	22	469	31	474	0.7	(0.38, 1.28)
Serious Adverse Event NOS/Death	Etidro	Calcium	1	8	81	20	85	0.36	(0.13, 0.92)*
Serious Adverse Event NOS/Death	Alendr	Estrog	2	47	185	57	236	0.9	(0.55, 1.49)
Serious Adverse Event NOS/Death	Pamidr	Estrog-Vit D	1	13	50	16	49	0.73	(0.28, 1.89)
Serious Adverse Event NOS/Death	Alendr	Vit D	4	40	384	41	364	0.97	(0.5, 1.89)
Serious Adverse Event NOS/Death	Alendr	placebo	28	2384	13566	1909	8573	0.96	(0.89, 1.03)
Serious Adverse Event NOS/Death	Calcit	placebo	5	13	255	7	184	1.46	(0.52, 4.54)
Serious Adverse Event NOS/Death	Etidro	placebo	8	54	440	68	453	0.78	(0.52, 1.18)
Serious Adverse Event NOS/Death	Ibandr	placebo	5	1339	4555	669	2207	0.99	(0.88, 1.11)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Serious Adverse Event NOS/Death	PTH	placebo	1	2	198	0	100	Inf+	(0.09, Inf+)
Serious Adverse Event NOS/Death	Pamidr	placebo	1	5	21	3	22	1.95	(0.32, 14.5)
Serious Adverse Event NOS/Death	Ralox	placebo	4	23	5353	13	2743	1.26	(0.48, 3.37)
Serious Adverse Event NOS/Death	Risedr	placebo	13	4607	15843	2498	8738	0.97	(0.92, 1.03)
Serious Adverse Event NOS/Death	Zoledr	placebo	2	39	347	23	110	0.79	(0.41, 1.57)
Serious Adverse Event NOS/Death: Death	Alendr	PTH	1	0	73	1	73	0	(0, 39)
Serious Adverse Event NOS/Death: Death	Alendr	Ralox	1	0	246	1	241	0	(0, 38.2)
Serious Adverse Event NOS/Death: Death	Etidro	Calcium	1	8	81	20	85	0.36	(0.13, 0.92)*
Serious Adverse Event NOS/Death: Death	Pamidr	Estrog-Vit D	1	13	50	16	49	0.73	(0.28, 1.89)
Serious Adverse Event NOS/Death: Death	Alendr	Vit D	4	3	384	6	364	0.49	(0.08, 2.32)
Serious Adverse Event NOS/Death: Death	Alendr	placebo	6	82	4243	70	3798	1.07	(0.76, 1.5)
Serious Adverse Event NOS/Death: Death	Calcit	placebo	3	5	57	4	55	1.26	(0.25, 6.88)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Serious Adverse Event NOS/Death: Death	Etidro	placebo	4	30	246	41	255	0.72	(0.41, 1.23)
Serious Adverse Event NOS/Death: Death	Ibandr	placebo	3	25	2153	13	1096	1.06	(0.52, 2.29)
Serious Adverse Event NOS/Death: Death	PTH	placebo	1	2	198	0	100	Inf+	(0.09, Inf+)
Serious Adverse Event NOS/Death: Death	Ralox	placebo	2	6	5224	0	2624	Inf+	(0.59, Inf+)
Serious Adverse Event NOS/Death: Death	Risedr	placebo	2	11	390	12	390	0.91	(0.36, 2.3)
Serious GI	Alendr	Pamidr	1	5	21	2	19	2.59	(0.36, 30.9)
Serious GI	Alendr	Risedr	1	1	219	1	222	1.01	(0.01, 79.9)
Serious GI	Alendr	Vit D	2	3	179	1	180	3.06	(0.24, 162)
Serious GI	Alendr	placebo	23	301	15545	274	10957	0.98	(0.83, 1.17)
Serious GI	Etidro	placebo	6	254	8199	383	16222	1.32	(1.12, 1.55)*
Serious GI	Ibandr	placebo	3	95	4356	60	2086	0.78	(0.55, 1.1)
Serious GI	Pamidr	placebo	4	7	126	0	107	Inf+	(1.01, Inf+)*
Serious GI	Ralox	placebo	2	72	5316	26	2673	1.4	(0.88, 2.29)
Serious GI	Risedr	placebo	11	208	15754	179	8478	0.92	(0.74, 1.14)
Serious GI: Esoph, inc esoph ulcers	Alendr	placebo	11	58	13313	31	9503	1.47	(0.92, 2.39)
Serious GI: Esoph, inc esoph ulcers	Etidro	placebo	1	126	7977	190	15954	1.33	(1.05, 1.68)*
Serious GI: Esoph, inc esoph ulcers	Ibandr	placebo	1	5	1954	2	975	1.25	(0.2, 13.1)

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Serious GI: Esoph, inc esoph ulcers	Pamidr	placebo	1	4	33	0	16	Inf+	(0.32, Inf+)
Serious GI: Esoph, inc esoph ulcers	Risedr	placebo	8	52	14368	35	7294	0.75	(0.48, 1.18)
UGI	Alendr	Pamidr	1	5	21	2	19	2.59	(0.36, 30.9)
Serious GI:UGI PUBs, excl esoph	Alendr	Risedr	1	0	219	1	222	0	(0, 39.5)
Serious GI:UGI PUBs, excl esoph	Alendr	Vit D	2	3	179	1	180	3.06	(0.24, 162)
Serious GI:UGI PUBs, excl esoph	Alendr	placebo	14	156	8935	153	7896	0.95	(0.75, 1.2)
Serious GI:UGI PUBs, excl esoph	Etidro	placebo	3	123	8066	186	16083	1.32	(1.04, 1.67)*
Serious GI:UGI PUBs, excl esoph	Ibandr	placebo	2	11	2445	16	1137	0.33	(0.14, 0.76)*
Serious GI:UGI PUBs, excl esoph	Pamidr	placebo	3	3	93	0	91	Inf+	(0.41, Inf+)
Serious GI:UGI PUBs, excl esoph	Risedr	placebo	7	26	2927	16	1993	0.93	(0.47, 1.87)
Special Senses	Ibandr	placebo	3	320	2462	171	1158	0.9	(0.73, 1.11)
Special Senses	PTH	placebo	1	1	17	0	17	Inf+	(0.03, Inf+)
Special Senses	Ralox	placebo	2	745	5316	407	2673	0.91	(0.79, 1.04)
Special Senses: Cataracts	Ibandr	placebo	1	1	1911	0	949	Inf+	(0.01, Inf+)
Special Senses: Cataracts	Ralox	placebo	1	745	5129	406	2576	0.91	(0.8, 1.04)
Upper Respiratory	Alendr	Calcit	1	0	118	6	123	0	(0, 0.87)*

Appendix F. Adverse Events Analyses

				Drug 1		Drug 2			
Event Category	**drug1**	**drug2**	**# studies**	**# events**	**sample size**	**# events**	**sample size**	**OR**	**95% CI**
Upper Respiratory	Calcit	Vit D	1	7	49	0	50	Inf+	(1.59, Inf+)*
Upper Respiratory	Calcit	placebo	6	233	1426	48	629	1.98	(1.4, 2.83)*

Alendr	Alendronate
Calcit	Calcitonin
CI	confidence interval
Esoph, inc esoph ulcers	
Estrog	Estrogen
Etidro	Etidronate
GI	Gastrointestinal
Ibandr	Ibandronate
Inj/app site rxns	Injection/ application site
iu	international units
IV	Intravenous
LFTs	Liver function tests
N/V	Nausea/vomiting
OR	Odds ratio
Pamidr	Pamidronate
PTH	Parathyroid hormone
Ralox	Raloxefine
RCT	randomized controlled trial
Rflx or esoph sx	Reflux or esophageal symptoms
Risedr	Risedonate
Tamox	Tamoxifen
Testos	Testosterone
UGI	Upper Gastrointestinal
Vit D	Vitamin D
Zoledr	Zolendronic Acid