**Table B14. Osteoporosis: Data Abstraction: Study Characteristics**

|  | **Publication, methods section** |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, year** | **Study design** | **Intervention** | **Comparison** | **Total N** | **Primary outcome as stated in the study (relevant to index outcome)** | **Relevant secondary outcomes (relevant to index outcome)** | **Followup intervals (months or years)  F/U 1  F/U 2  F/U 3** | **Analysis set (definition from study)  Definition of analysis set** | **How handled missing values** | **Subgroups specified in the methods section** |
| Barrett-Connor, 2006 | Parallel group | Raloxifene | Placebo | 10,101 | None | Fracture; clinical nonvertebral and vertebral | Median 5.6 years range, 0.01 to 7.06  NA  NA | ITT  NR | NA (time-to-event data for primary outcomes) | None for fractures |
| Black, 2007 | Parallel group placebo RCT | Zoledronic acid | Placebo | 3889 | New vertebral fracture (in patients not taking concomitant osteoporosis medications) and hip fracture (in all patients) | Secondary efficacy endpoints: any nonvertebral fracture, any clinical fracture, and clinical vertebral fracture | 12 m  24 m  36 m | Efficacy analyses included all patients who had undergone randomization except for 29 whose site was terminated.  The incidence of vertebral fracture included patients who had undergone radiography at baseline at least once during F/U. | NR | NR |
| Bonnick, 2006  NOTE: this is a companion to Rosen 2005 | Parallel group RCT, extension study of Rosen 2005 | Alendronate | Risedronate | 833 | None | None | 12 month extension after initial 12 months  NA  NA | For safety outcomes, all patients who received at least one dose of study medication in the extension period | NA for safety outcomes | None |
| Grant, 2005 | Factorial design, parallel group | Oral vitamin D3 combined with calcium | Placebo | 5292 | All-new low-energy fractures including clinical, radiologically confirmed vertebral fractures, but not those of the face or skull | None | 24 to 64 m  NA  NA | ITT  NR | NR | High or low weight (less than 55 kg or not); latitude of recruitment center; dietary calcium; and vitamin D exposure from the sun or diet |
| Greenspan, 2006 | Parallel group | Risedronate | Placebo | 87 | None | None | 12 m  24 m (extension)  NA | ITT  NR | NR | None |
| Jackson, 2006 | Parallel group | Elemental calcium as calcium carbonate with vitamin D3 | Placebo | 36,282 | Total fractures defined as all reported clinical fractures other than ribs, face, etc. | None | 7 years average  NA  NA | Time-to-event basis according to the ITT principle  NR | NR |  |
| McClung, 2006 | Parallel group, placebo control and active control RCT | Denosumab; alendronate | Placebo | 412 | None | None | 12 m  NA  NA | Efficacy analyses: ITT Fractures were reported as a safety outcome and that analysis set was no specified explicitly (was n=406 from adverse event table). All subjects with a baseline value and at least one value after baseline and compared across dose groups. | NR | NA |
| Porthouse, 2005 | Parallel group RCT, open label | Calcium with cholecalciferol and information leaflet on dietary calcium intake and prevention of falls | Leaflet only | 3454 | All clinical fractures | Hip fractures | 25 months (range 18 to 42 months)  NA  NA | ITT  NR | NR | Hip and wrist fractures |
| Prince, 2006 | Parallel group | Calcium carbonate | Placebo | 1460 | Clinical incident osteoporotic fractures, vertebral deformity, and adverse events ascertained in 5 years | None | 5 y  NA  NA | ITT  NR | NR | Patients consuming 80% or more of tablets |
| Reid, 2006 | Parallel group | Calcium | Placebo | 1471 | Time to first clinical fracture at any site | Fracture subgroups: total vertebral fractures, hip fractures, distal forearm fractures, and osteoporotic fractures (comprising all fractures except those of the head, hands, feet, and ankles, and resulting from major trauma). | "Over 5 years"  NA  NA | ITT and per protocol  Per protocol pre-specified as primary analysis "because of the likelihood that other anti-osteoporotic therapies would have much greater effects on bone density and fracture than calcium…"   NR | NR | Total vertebral fractures, hip fractures, distal forearm fractures, and osteoporotic fractures |
| Rosen, 2005  NOTE: this is a companion to Bonnick 2006 but has separate NCT number | Parallel group RCT | Alendronate | Risedronate | 1053 | None | None | 6 m  12 m  NA | ITT  All patients who received at least one dose of study drug in either treatment group for safety analyses | LOCF | None |
| Vogel, 2006 | Parallel group RCT | Tamoxifen | Raloxifene | 19747 | None | Osteoporotic fractures | 5 y  NA  NA | ITT  All randomized participants with followup data who were at risk at baseline for the diagnosis of an incident case of breast cancer | NR | None |