will present preliminary two-year BMD results from a one-year extension.

Objectives

Methods We compared the efficacy of treatment with OW ALN 70 mg (n = 519), TW ALN 35 mg (n = 369), and OD ALN 10 mg (n = 370) over 2 years in a double-blind, multicenter study of postmenopausal women (age 40 to 90) with osteoporosis (BMD of either the lumbar spine or femoral neck ≥ 2.5 SDs below peak mean, or prior vertebral or hip fracture). The primary efficacy endpoint was change in lumbar spine BMD. Secondary endpoints included changes in BMD at the hip and total body.

Results Mean BMD increases at the lumbar spine, total hip, femoral neck, hip trochanter, and total body sites for each treatment regimen after two years were very similar, with no clinically meaningful differences.

Conclusion These findings confirm that once-weekly ALN 70 mg is therapeutically equivalent to once-daily ALN 10 mg in patients with postmenopausal osteoporosis. In addition, the two-year results demonstrate that once-weekly ALN 70 mg is generally as safe and well tolerated as ALN 10 mg once daily.

REFERENCE

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SAT0165 THE EFFECT OF ALENDRONATE ON AGE-SPECIFIC INCIDENCE OF KEY OSTEOPOROTIC FRACTURES

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10.1136/annrheumdis-2001.652

Background

Objectives To describe the behaviour of the relative risk (RR), absolute risk reduction (ARR), and number needed to treat (NNT) by attained age for the hip, spine or forearm for alendronate treatment in women with osteoporosis.

Methods 3658 women with osteoporosis from the Fracture Intervention Trial were followed for 3 to 4.5 years and treated with alendronate (ALN) at 5 mg/day for 2 years followed by 10 mg/day for the remainder of the trial. The age groups used in the analysis were: 55–65, 65–70, 70–75 and 75–85. All fractures were confirmed by x-rays.

Results Risk reduction of hip, spine and forearm fractures were 53% (RR = 0.47, p < 0.01), 45% (RR = 0.55, p < 0.01) and 30% (RR = 0.70, p = 0.038) respectively. The reductions did not depend on age. The ARR increased with age for each of the fracture sites. For the hip, the ARR increased from 0.13 women per 100 patient-years at risk (PYR) for the 55 to 65 group to 0.53 women per 100 PYR for the 75 to 85 group. The corresponding increases in ARR for the spine were 0.14 and 0.86. The NNTs for 5 years for the hip were 157 for the 55–65 year old and 45 for the 75 to 85 year old women. The corresponding numbers for the spine were 140 and 23. For the composite endpoint, the NNTs (for 5 years) were 38, 25, 17 and 13 for the age groups 55–65, 65–70, 70–75 and 75–85 respectively.

Conclusion Alendronate is very effective in reducing the risk of osteoporotic fractures, regardless of age.

SAT0166 ALENDRONATE REDUCES THE RISK OF CLINICAL VERTEBRAL FRACTURE IN OSTEOPENIC WOMEN: DATA FROM FIT

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10.1136/annrheumdis-2001.653

Background

Objectives To determine the effectiveness of alendronate in reducing the risk of clinical vertebral fractures (CVFX) in women with osteopenia who do not meet the BMD criterion for osteoporosis.

Methods We studied 3737 women, age 55 to 80, from the Fracture Intervention Trial who had BMD T-score > -2.5 at the femoral neck: 940 with an existing morphometric vertebral fracture (MVFX) and 2797 without. 1859 were treated with PBO and 1878 were treated with ALN 5 mg per day for the first two years and 10 mg for the remaining period for up to 2.5 years. All CVFX were confirmed by a physician.

Results The absolute risk of CVFX was about 4 to 5 fold greater in women with existing MVFX than in those without. Alendronate significantly (p = 0.005) reduced the overall risk of CVFX by 60% (RR = 0.40 (0.19, 0.76)). The reductions were consistent among those with and without MVFX: 0.34 (0.12, 0.84) and 0.46 (0.16, 1.17) respectively. The effect was observed very early. There were no CVFX in the first year among the alendronate patients.

Conclusion Alendronate was equally effective in reducing the relative risk of painful clinical vertebral fractures in women with and without existing MVFX. The effect of alendronate was seen early.

SAT0167 SAFETY OF ONCE-WEEKLY ALENDRONATE 70 MG IN PERIODONTAL DISEASE

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10.1136/annrheumdis-2001.654

Background Periodontal disease, the leading cause of tooth loss in adults, is a chronic inflammatory process which leads to a local imbalance between bone formation and bone resorption. Alendronate sodium (ALN) is a potent and selective inhibitor of osteoclastic bone resorption used for the treatment and prevention of osteoporosis in postmenopausal women. In postmenopausal osteoporotic women, ALN 70 mg once weekly has demonstrated efficacy comparable to those of ALN 10 mg daily and very good safety and tolerability. However, there has been no direct comparison between ALN 70 mg once weekly and placebo.

Objectives

Methods To further investigate the safety profile of once weekly ALN, as well as efficacy in periodontal disease, we are conducting a randomised, placebo-controlled, multicenter, 2-year study. Three-hundred and thirty-five patients aged 30 to 79 with