

[2008] [SAT0340] STRONTIUM RANELATE DECREASES THE RISK OF HIP FRACTURE OVER 3 AND 5 YEARS IN POST MENOPAUSAL WOMEN AT HIGH RISK

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Objectives: Strontium ranelate is an effective anti-osteoporotic treatment with a unique mode of action increasing bone formation while decreasing bone resorption. Anti-fracture efficacy of strontium ranelate was previously demonstrated at vertebral and non-vertebral levels. This new analysis over 3 and 5 years assess the efficacy of strontium ranelate against hip fractures.

Methods: In the TROPOS phase III study, 5091 Caucasian women with postmenopausal osteoporosis have been enrolled with mean age(SD) of 76.8(5) years and with mean femoral neck BMD T-score(SD) of -3.1(0.6). The patients were randomly assigned to receive strontium ranelate 2g/day or placebo for 5 years, all received supplementation with calcium and vitamin D adapted to their needs. The efficacy of strontium ranelate against hip fracture was assessed in a subset of osteoporotic women at high risk of such fracture (N=1126: N=557 strontium ranelate group and N=569 placebo group; new post-hoc analysis) aged 74 years (threshold for large increase in hip fracture risk) or older and with lumbar and femoral neck BMD T- score<-2.4 (NHANES normative values).

Results: The baseline characteristics of patients were similar in both groups (mean age(SD) 79.2(4.4), mean lumbar T-score -4.2, mean hip T-score -3.4). Over 3 years of treatment, strontium ranelate reduced the risk of hip fracture by 45% (RR=0.55; 95%CI[0.30;0.99], p=0.049; incidence: strontium ranelate 4.0% vs. placebo group 6.3%). This hip anti-fracture efficacy was sustained over 5 years with a 43% reduction of the risk (RR=0.57;95% CI[0.33;0.97]; p=0.036; incidence: 7.2% vs.10.2%). The reduction in the risk of hip fracture is paralleled by a significant increase after 3 and 5 years by 5.6% and 6.5% of the relative change from baseline of the hip BMD respectively (p<0.001 vs. placebo in both cases).

Conclusion: This work demonstrates the efficacy over 3 and 5 years of strontium ranelate in reducing the risk of hip fracture in post menopausal osteoporotic women at high risk of such fracture.

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Osteoporosis

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