Efficacy and safety of strontium ranelate in the treatment of osteoporosis in men

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CONTEXT: Strontium ranelate reduces vertebral and nonvertebral fracture risk in postmenopausal osteoporosis.

OBJECTIVE: The objective of this study was to determine the efficacy and safety of strontium ranelate in osteoporosis in men over 2 years (main analysis after 1 year).

DESIGN: This was an international, unbalanced (2:1), double-blind, randomized placebo-controlled trial (MALEO [MALE Osteoporosis]).

SETTING: This international study included 54 centers in 14 countries.

PARTICIPANTS: PARTICIPANTS were 261 white men with primary osteoporosis.

INTERVENTION: Strontium ranelate at 2 g/d (n = 174) or placebo (n = 87) was administered.

MAIN OUTCOME MEASURES: Lumbar spine (L2-L4), femoral neck, and total hip bone mineral density (BMD), biochemical bone markers, and safety were measured.

RESULTS: Baseline characteristics were similar in both groups in the whole population (age, 72.9 ± 6.0 years; lumbar spine BMD T-score, -2.7 ± 1.0; femoral neck BMD T-score, -2.3 ± 0.7). Men who received strontium ranelate over 2 years had greater increases in lumbar spine BMD than those who received placebo (relative change from baseline to end, 9.7% ± 7.5% vs 2.0% ± 5.5%; between-group difference estimate (SE), 7.7% (0.9%); 95% confidence interval, 5.9%-9.5%; P < .001). There were also significant between-group differences in relative changes in femoral neck BMD (P < .001) and total hip BMD (P < .001). At the end of treatment, mean levels of serum cross-linked telopeptides of type I collagen, a marker of bone resorption, were increased in both the strontium ranelate group (10.7% ± 58.0%; P = .022) and the placebo group (34.9% ± 65.8%; P < .001). The corresponding mean changes of bone alkaline phosphatase, a marker of bone formation, were 6.4% ± 28.5% (P = .005) and 1.9% ± 25.4% (P = .505), respectively. After 2 years, the blood strontium level (129 ± 66 μmol/L) was similar to that in trials of postmenopausal osteoporosis. Strontium ranelate was generally well tolerated.

CONCLUSIONS: The effects of strontium ranelate on BMD in osteoporotic men were similar to those in postmenopausal osteoporotic women, supporting its use in the treatment of osteoporosis in men.


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