

New class drug significantly reduces spine fracture risk in postmenopausal women with osteoporosis

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The results of a study presented today at the Annual European Congress of Rheumatology (EULAR) 2017 show that in postmenopausal women with osteoporosis, 12 months of treatment with romosozumab is associated with large, rapid reductions in their risk of a vertebral fracture compared to placebo.

In those women receiving romosozumab, all clinical vertebral [fractures](#) occurred in the first two months of treatment; overall, the risk of a vertebral fracture was more than five times greater in the group of women given placebo.

"These results support this new class of drug as a highly effective treatment for postmenopausal women who have osteoporosis with established [bone mineral density](#) (BMD) deficit who are at increased risk of fracture," said Professor Piet Geusens, lead author from Maastricht University, The Netherlands. "The rapid and large reduction in clinical vertebral fracture risk is an important and highly relevant clinical outcome," he added.

Romosozumab is a monoclonal antibody that binds and inhibits sclerostin (a glycoprotein produced by bone cells). This action has the dual effect of increasing bone formation and decreasing bone resorption, resulting in significant increases in BMD. Previous studies have shown that romosozumab, administered subcutaneously at monthly intervals

over a period of 12 months, resulted in gains in both the trabecular and cortical compartments of the spine and hip regions.

The Fracture Study in Postmenopausal Women with Osteoporosis (FRAME) is an international, randomised, double-blind, placebo-controlled, parallel-group trial. FRAME enrolled 7,180 postmenopausal women, 55-85 years old, with evidence of osteoporosis confirmed by abnormally low [bone](#) density scores in their spine, hip, and femoral neck, but no severe vertebral fracture. Patients received monthly romosozumab (n=3,589) or placebo (n=3,591) for 12 months.

Initial results from FRAME had shown romosozumab was associated with a lower risk of new vertebral fractures than placebo at 12 months. The effect of romosozumab on the risk of vertebral fracture was rapid, with only 2 additional vertebral fractures (of a total of 16 such fractures in the romosozumab group) occurring in the second 6 months of therapy.

These new data from FRAME focussed on the incidence of clinical vertebral fracture in those women in the study who developed back pain consistent with this diagnosis. Monthly study visits in FRAME enabled timely X-ray confirmation of any suspected clinical vertebral fracture.

Of those 119 women reporting back pain over 12 months, 20 were diagnosed with a new or worsening vertebral fracture. In the romosozumab group, there were 3 clinical vertebral fractures (

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