Romosozumab Reduces Risk of Fractures in Women with Osteoporosis

Postmenopausal women with osteoporosis who were treated with romosozumab had a significantly lower fracture risk compared with those who were treated with only alendronate in a phase 3 trial.

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October 28, 2019 – Postmenopausal women treated with romosozumab followed by alendronate had a 48% lower risk of vertebral fractures compared with those treated with alendronate alone.

Kenneth G. Saag, MD, with the University of Alabama, and his colleagues on the ARCH study, reported their findings in the October 12, 2017, issue of the *New England Journal of Medicine.*

Postmenopausal women with osteoporosis are at risk for bone fractures that may increase the risk of mortality. Romosozumab is a monoclonal antibody that has a positive effect on bone formation and bone resorption. Alendronate–one of the most common treatments for osteoporosis–on the other hand, only inhibits bone resorption. The ARCH study compared the effects of a treatment regimen that included romosozumab followed by alendronate with alendronate alone, in postmenopausal women between the ages of 55 to 90 years.

In this phase 3, randomized, double-blind trial, 4093 postmenopausal women with osteoporosis and a previous fracture were treated with either romosozumab (210 mg subcutaneous, monthly) or alendronate (70 mg oral, weekly) for 12 months. Following this treatment period, all study participants were given alendronate (70 mg oral, weekly) for 12 months.

After the 24-month treatment period, those participants who received romosozumab followed by alendronate had a 48% lower risk of new vertebral fractures in comparison with those who received alendronate alone (6.2% vs 11.9%; risk ratio, 0.52; 95% confidence interval, 0.40 to 0.66; $P<0.001$). Romosozumab followed by alendronate also resulted in a 27% lower risk of clinical fracture (hazard ratio, 0.73; 95% CI, 0.61 to 0.88; $P<0.001$). The risk of nonvertebral fractures was also lower (by 19%) in the romosozumab followed by alendronate group (hazard ratio, 0.81; 95% CI, 0.66 to 0.99; $P=0.04$).

This study also measured the effect of the treatment regimens on bone density. The participants who received romosozumab showed increased and maintained gains in bone mineral density compared with those who received alendronate alone.

Adverse events were similarly reported between the 2 study groups, with back pain appearing to be the most common. However, serious cardiovascular events (including cardiac ischemic and cerebrovascular) were more frequently observed in the romosozumab group.

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