

Denosumab treatment for postmenopausal osteoporosis increases bone density

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Postmenopausal women with osteoporosis who take denosumab long-term have increased bone density, sustained low rate of fractures, and a favorable benefit/risk profile, a new multinational study finds. The results were presented Sunday, June 22, at ICE/ENDO 2014, the joint meeting of the International Society of Endocrinology and the Endocrine Society in Chicago.

"This study provides reassurance to physicians and their patients that long-term treatment with [denosumab](#) for at least 8 years leads to significant increases in bone density and is safe for appropriately selected women with postmenopausal osteoporosis," said lead study author E. Michael Lewiecki, MD, clinical assistant professor of medicine at the University of New Mexico School of Medicine in Albuquerque. "It's important to note that the overall risk of side effects did not increase over time."

Osteoporosis is a long-term disease that occurs when the creation of new bone doesn't keep up with the removal of old bone. The disorder primarily affects women past menopause, causing their bones to become weak and brittle, sometimes so much so that a fall or even a cough can cause a fracture. The treatments that reduce fracture risk by increasing bone density have important long-term effects.

This study showed that long-term treatment with denosumab was safe and resulted in continuing increases in [bone density](#) over the 8 years of treatment, with persistently low fracture rates.

To evaluate the long-term efficacy and safety of denosumab for up to 10 years, Dr. Lewiecki and his colleagues conducted the ongoing multinational FREEDOM clinical trial. In this study, the researchers present data from up to 8 years of continued denosumab treatment.

Among the almost 8,000 women originally enrolled

in the FREEDOM trial, denosumab reduced their risk of vertebral [fractures](#) by 68%, reduced their risk of hip fractures by 40%, and reduced their risk of nonvertebral fractures by 20%, compared with placebo. The women taking the drug had no increase in their overall risk of cancer, infection, cardiovascular disease, delayed fracture healing, or hypocalcemia.

All the roughly 3,000 [women](#) in this long-term extension of the trial took denosumab for up to 8 years, and overall, they showed a continued increase in their mean [bone mineral density](#), with a cumulative 8-year gain of 18.4% at the lumbar spine and 8.3% at the total hip, with few fractures and a good safety profile.

Provided by The Endocrine Society

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