

Study shows drug effectiveness in reducing glucocorticoid-induced bone loss

April 25 2018, by Jeff Hansen

About one in every 100 people in the world takes glucocorticoids long term to treat immune-mediated diseases. However, glucocorticoids, such as prednisone, have a side effect—they induce the bone loss called osteoporosis, causing an estimated yearly bone fracture rate of 5 percent.

An alternative treatment option now appears promising, according to results of an international study published in the journal *The Lancet Diabetes & Endocrinology*. The study was headed by Kenneth Saag, M.D., the Jane Knight Lowe Professor of Medicine at the University of Alabama at Birmingham.

Saag and colleagues compared the monoclonal antibody <u>denosumab</u> against a standard treatment for glucocorticoid-induced secondary osteoporosis, the bisphosphonate <u>risedronate</u>. In the 12-month results of their 24-month study, they have found that denosumab was superior to risedronate, as measured by increased <u>bone density</u> in the lower spine.

"To our knowledge, ours is the first large, randomized controlled trial of denosumab in patients with glucocorticoid-induced osteoporosis who were either prevalent glucocorticoid users or newly initiating glucocorticoid therapy," they wrote. "Denosumab could be a useful addition to the treatment armamentarium for glucocorticoid-induced osteoporosis."

The double-blind study enrolled 795 patients at 79 health care centers in Europe, Latin America, Asia and North America. Of these, 505 were



glucocorticoid-continuing patients who had received glucocorticoids for at least three months, and 290 were glucocorticoid-initiating <u>patients</u> who had received glucocorticoids for less than three months.

Patients were randomly assigned to one of two groups. The denosumab group got a shot of denosumab underneath the skin every six months and took a placebo pill every day. The risedronate group got a placebo shot every six months and took oral risedronate every day.

Besides the superior lumbar spine bone density with denosumab after 12 months, researchers also found that denosumab was superior to risedronate for bone density measured in the total hip and at the neck of the femur, the large <u>bone</u> of the thigh.

The two treatment groups had similar safety profiles.

The researchers note that the study compared denosumab with risedronate, so the relative performance of denosumab compared with osteoporosis treatments besides risedronate has not yet been established.

More information: Kenneth G Saag et al. Denosumab versus risedronate in glucocorticoid-induced osteoporosis: a multicentre, randomised, double-blind, active-controlled, double-dummy, non-inferiority study, *The Lancet Diabetes & Endocrinology* (2018). DOI: 10.1016/S2213-8587(18)30075-5

Provided by University of Alabama at Birmingham

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