Therapy of the Skeletal Disease of Type 2 Diabetes With Denosumab

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Given the established deficits in type 2 diabetes (T2D) in microstructure and bone material properties, denosumab (DMAb) is an attractive therapeutic agent in the skeletal disease of T2D. In postmenopausal women without T2D, DMAb decreases bone resorption and reduces cortical porosity at the extremities and at the hip. Yet clinical evidence is lacking for the anti-osteoporotic efficacy of DMAb in T2D patients. The hypothesis of this study was that DMAb will improve indices of bone strength in T2D. To determine whether DMAb treatment in T2D improves bone quality, this study was initiated.

The study was a 12 month randomized (2:1 assignment) double-blind placebo controlled trial of T2D postmenopausal women assigned to either DMAb 60 mg SC at baseline and 6 months (n=44) or placebo (n=22); total study n=66. The statistical analysis plan was as follows: the primary outcome was the 1-year change in cortical porosity and the primary intent-to-treat analysis was a one-way ANCOVA with fixed effect of treatment (treated *vs.* placebo). The study assessments consisted of a Screening Visit, a Baseline Visit, and 3, 6 and 12 Month Visits. Screening occurred within 31 days of the Baseline Visit. Subjects who met the inclusion/exclusion criteria as specified in the protocol were randomized at the Baseline Visit. All participants were given calcium 800 mg/d and vitamin D 1000 IU/day as needed to achieve a total calcium daily intake (from diet and supplements) of at least 1200 mg/d.

The study was terminated by Amgen Inc. on June 10, 2020 because of insufficient patient recruitment that was exacerbated by the COVID pandemic. Eight subjects had been enrolled. After unblinding, the subjects who received active drug (n=4) were transitioned to alendronate within 7 months after the last study drug injection.