

## **The Use of Teriparatide (Forteo) as an Adjunctive Therapy for the Treatment of Jones Fractures**

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### **Study Synopsis**

Healing of problematic fractures has long been a focus in orthopedic surgery. Many treatments have been suggested to enhance healing of difficult fractures, such as distal radius fractures, anterior tibial stress fractures, navicular fractures, talar neck fractures, and fifth metatarsal Jones fractures. Treatments, including dynamic bracing, electrical stimulation and various surgical options, have met with variable success. Previous teriparatide research leads us to believe that it may be a promising adjunctive therapy for the treatment of problematic fractures. Jones fracture was selected as a model for study for several reasons, including lengthy time to union, variability in the time to achieve complete fracture healing, a source of chronic pain, and susceptibility to reinjury. Currently, no studies have been reported evaluating fracture healing after the adjunctive use of teriparatide for the treatment of Jones fractures.

Thirty eight patients will be randomized into one of two groups. Patients randomized into the experimental group will inject 20 mcg of teriparatide once daily, whereas patients randomized into the control group will inject a matching dose of the placebo once daily. The primary efficacy objective is to determine whether patients randomized to the teriparatide group have superior fracture healing of the fifth metatarsal (Jones fracture), as assessed by plain radiographs, compared to patients randomized to the placebo group. Secondary efficacy objectives include determining whether patients randomized to the teriparatide group have superior outcomes compared to patients randomized to the placebo group in terms of (1) Visual Analog Pain Scale; (2) range of motion; (3) the AOFAS Midfoot Scale scores; and (4) return to activity.

Because previous literature evaluating fracture healing of Jones fractures have relied solely on plain radiographs, this study also will quantify callus mineralization using peripheral quantitative computed tomography (pQCT) to further evaluate fracture healing. Previously, pQCT has demonstrated accurate measures of bone mineral density and bone mineral content at various skeletal sites and also has been used to monitor decreases in bone mass. Peripheral quantitative CT may also provide viable information regarding complications that may arise in the healing process, such as in the cases of delayed unions or nonunions.

We anticipate that the adjunctive use of teriparatide will significantly improve fracture healing of the fifth metatarsal, with potential secondary benefits of pain reduction, improved early function, increased range of motion, and quicker return to activity. Because the Jones fracture model has enough variability in time to healing, the magnitude of difference in healing time between fractures treated with and without teriparatide may be discerned. Therefore, we believe that this study has the potential of being a landmark study documenting teriparatide's speed of healing. By showing the drug's potential to affect the process of fracture healing; its use may be extrapolated to other problematic fractures.

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