

The FaB (Fractures and Bisphosphonates) Trial: A Multicenter, Double-Blind, Randomized Controlled Trial on the Effect of Alendronic Acid on Healing and Clinical Outcomes of Wrist Fractures

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Purpose: There is currently no consensus on whether bisphosphonate therapy should be withheld following a low-energy fracture of the distal radius due to the potential concerns about an adverse effect on bone healing. The primary aim of this multicenter, double-blind, randomized placebo controlled trial was to determine if there is any difference between alendronic acid versus placebo on the union rate at 4 weeks post treatment in patients ≥ 50 years who have sustained a fracture of the distal radius. The null hypothesis was that there is no difference in union rates between groups at 4 weeks post treatment.

Methods: We performed a registered multicenter ($n = 15$), double-blind, randomized placebo controlled trial in 421 patients ≥ 50 years of age with an acute radiographically confirmed nondisplaced or displaced fracture of the distal radius. Patients were randomized to either alendronic acid 70 mg once weekly ($n = 215$) or placebo ($n = 206$), and were reviewed at 2 weeks, 4 weeks, 6 weeks, 2 months, and 6 months following injury. The primary outcome measure was the percentage of fractures united at 4 weeks.

Results: The baseline demographic and fracture characteristics of the 2 groups were comparable. The 4-week follow-up rate was 92% ($n = 389$) and the 6-month follow-up rate was 90% ($n = 380$). Study treatment compliance was 85.2% ($n = 359$). There was no statistically significant difference (-4.1%; 95% confidence interval [CI], -12.8 to 4.7; $P = 0.53$) in fracture union rates between the alendronic acid group (23.8%; 95% CI, 17.9 to 29.6) or the placebo group (27.8%; 95% CI, 21.4 to 34.2) at 4 weeks. No difference was also seen in union rates at 6 weeks (44.6% vs 44.2%; $P = 0.88$) or 2 months (61.7% vs 56.3%; $P = 0.19$). There was also no difference at any time point between the 2 groups in terms of the Disabilities of the Arm, Shoulder and Hand (DASH), pain, grip strength, malunion rates, or the prevalence of complex regional pain syndrome ($P > 0.05$ for all).

Conclusion: This large multicenter trial demonstrated that the early administration of alendronic acid did not alter fracture union rates or clinical outcome when compared to placebo in patients ≥ 50 years who sustain a fracture of the distal radius. We would recommend that there is no indication for clinicians to withhold bisphosphonate therapy in patients who sustain a fracture of the distal radius. Further work is required to determine if this practice can be adapted for other osteoporotic fractures.