A Pilot Feasibility, 2 x 2 Factorial Randomized Controlled Trial Comparing the Sliding Hip Screw versus Cancellous Screws and Vitamin D3 versus Placebo for the Treatment of Young Femoral Neck Fractures

FAITH-2 Trial Investigators
McMaster University, Hamilton, ON, Canada

Purpose: The treatment of young femoral neck fractures remains controversial because the optimal internal fixation implant is unknown and the implications of treatment failures can profoundly impact functional outcome. Additionally, the use of adjuvant vitamin D3 supplementation to improve outcomes after fracture remains unproven. The purpose of this trial was to determine the feasibility of a definitive multicenter randomized controlled trial comparing the sliding hip screw (SHS) and cancellous screws (CS), and vitamin D3 versus placebo for the treatment of femoral neck fractures in young patients.

Methods: Adult femoral neck fracture patients ages 18-60 yearswere enrolled from 15 North American hospitals. A 2 x 2 factorial design was used to randomly allocate patients to SHS or CS and to vitamin D3 4000 IU or placebo daily for 6 months. The primary outcome was trial feasibility, defined by measures of recruitment, medication adherence, and data quality. The secondary outcome was a composite outcome of clinically important complications, including reoperation, nonunion, osteonecrosis, and fracture shortening >1 cm.

Results: We randomized 91 patients over a 4-year period, and 86 participants were included in the analysis. The mean age of participants was 41.1 years (standard deviation 12.4). 71% of fractures were displaced and 44% were vertical Pauwels 3 patterns. The primary feasibility criteria were not achieved due to slow enrollment and low vitamin D adherence, with only 55% of participants taking ≥75% of their daily supplement. 14 patients in the CS group (33%) and 11 patients in the SHS group (26%) experienced the composite complication outcome; reoperations accounted for 7 (16%) CS events and 9 (21%) SHS events. There were 3 conversions to total hip arthroplasty (THA) in the SHS group and 1 conversion to THA in the CS group. There were 2 cases in the CS group (5%) and 1 case (2%) in the SHS group of isolated femoral neck shortening >1 cm that did not result in femoral head osteonecrosis or a reoperation. A composite complication occurred in 14 patients (35%) in the placebo group and in 11 patients (24%) in the vitamin D group. There were no vitamin D-related adverse events reported.

Conclusion: This pilot study was unable to demonstrate the feasibility of a definitive trial. The adherence with daily vitamin D3 supplementation is low among young femoral neck fracture patients and is unlikely to be an effective method of supplementation. Overall, >25% of young femoral neck fracture patients experience complications of their injury.