

**•GROWTH HORMONE TREATMENT OF TIBIAL FRACTURES:  
A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL**

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**INTRDUCTION**

Despite improvements in surgical techniques, treatment of tibial fractures remains a challenge in orthopaedic surgery. The purpose of this study was to investigate the efficacy and safety of hGH for the treatment of tibial fractures surgically fixed with intramedullary nailing

**SUBJECTS & METHODS**

**Patients** 407 patients with open (29%) and closed tibial fractures were randomised. Male (75%) and female patients aged  $\geq 18$  years and  $< 65$  years.

The patients were stratified by fracture (open or closed). Within each stratum, the patients were randomly allocated to either hGH (Norditropin® SimpleXX®; 10 mg/cartridge) or placebo, at one of three dose levels: 15, 30 and 60  $\mu\text{g}/\text{kg}$  body weight. Trial product was administered daily by subcutaneous injections. Treatment was continued either until fracture healing or until 16 weeks post-surgery, whichever occurred first.

The patients reported for evaluation every 4 weeks until 24 weeks post-surgery, and at 9 and 12 months.

**Assessments:** X-rays of the injured tibia were taken pre- and post-surgery and at each visit. A fracture was radiologically defined as healed by disappearance of the fracture lines and/or cortical bridging in 3 out of the 4 cortices. X-rays were evaluated centrally by a panel of 3 experienced radiologists blinded to the treatment regimen.

**RESULTS:**

407 patients were randomised, and 368 (90%) completed the trial. During the 12 months study period, the relative risk of fracture healing (60  $\mu\text{g}/\text{kg}$  vs. placebo) was: all fractures, 1.16; 95% CI:[0.86;1.57](ns); closed fractures, 1.44; 95% CI:[1.01;2.05] ( $p < 0.05$ ); open fractures, 0.75; 95% CI [0.42; 1.31] (ns).

Adverse events were consistent with those usually seen in tibial fractures (infections) or during hGH treatment in adults (peripheral edema, arthralgia).

**CONCLUSION:**

In closed tibial fractures separately, hGH treatment accelerated healing significantly, which may be of benefit in people with closed fractures. No new hGH safety issues were identified.

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