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

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INTRODUCTION

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 ≥ 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 µg/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 µg/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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