

Proximal Femoral Nail Unlocked versus Locked (ProFNUL): a protocol for a multicentre, parallel-armed randomised controlled trial for the effect of femoral nail mode of lag screw locking and screw configuration in the treatment of intertrochanteric femur fractures

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INTRODUCTION

Intertrochanteric fractures are common fragility injuries in the elderly. Surgical fixation using intramedullary devices are one of the widely used management options. To date, evidence demonstrating the effects of lag screw configuration and the mode of lag screw locking in these devices is lacking. The purpose of this study is to investigate whether the lag screw configuration (single vs integrated dual interlocking screw) and the mode of lag screw locking (static vs dynamic) of a femoral nail device result in differences in clinical and functional outcomes.

METHODS AND ANALYSIS

A multicentre, pragmatic, single-blinded randomised controlled trial (RCT) with a three-arm parallel group design is proposed. Nine-hundred patients with intertrochanteric fractures (A1 and A2 AO/OTA) will be randomised to fracture treatment using a Gamma3 nail (Stryker; proximally dynamic) or a Trigen Intertan nail (Smith & Nephew) in a dynamic or static lag screw configuration. The primary outcome measure consists of radiological evidence of construct failure within 6 months following surgery, with failure being defined as breakage of the femoral nail or distal locking screw, a change in tip-apex distance of more than 10 mm or lag screw cut-out through the femoral head. Secondary outcomes include surgical data (operation time, fluoroscopy time), complications (surgical site infection, reoperation, patient death), return to mobility and home circumstances, functional independence, function and pain. Patients who are able to walk independently with or without a mobility aid and are able to answer simple questions and follow instructions will be asked to participate in three dimensional gait analysis at 6 weeks and 6 months to assess hip biomechanics from this cohort. Additional secondary measures of gait speed, hip range of motion, joint contact and muscle forces and gross activity monitoring patterns will be obtained in this subgroup.

ETHICS AND DISSEMINATION

The Central Adelaide Local Health Network Human Research Ethics Committee has approved the protocol for this RCT (HREC/17/RAH/433). The results will be disseminated via peer-reviewed publications and presentations at relevant conferences.

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