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Surgical treatment of osteoporotic hip fractures

Submission date
13/04/2022

Recruitment status
No longer recruiting

Registration date
19/04/2022

Overall study status
Completed

Last Edited
31/07/2023

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hip fractures are an increasingly common consequence of falls in older people that are associated with a high risk of death and reduced function. In fact, hip fractures constitute one of the most common impairments worldwide in terms of loss in disability-adjusted years for people older than 60 years old. The consequences for hip fractures in elderly individuals are significant in terms of lives lost and the associated negative impacts on hip fracture patients' functioning and quality of life. The vast majority of intertrochanteric fractures require surgical treatment to withstand early mobilization and weight-bearing, which prevents complications due to prolonged bed rest and aids in fracture healing. The type of surgery is generally based on fracture pattern and patient characteristics and is usually carried out with Dynamic Hip Screw devices or cephalomedullary nails, which are less invasive and can provide not only biological fixation but also better support in more complex fracture patterns. The Trigen Intertan (TIT) nail is a third-generation device featuring a dual lag screw configuration that allows for linear compression of the fragments at the fracture site while providing high rotational stability. Clinical studies evaluating the Intertan nail against other single-screw intramedullary or extramedullary devices have shown controversial results. The aim of this study is to investigate if there are any significant differences between the classic single-screw cephalomedullary nail (SSCN) and the new dual lag-screw nail (InterTan-IT).

Who can participate?
Patients aged over 70 years with closed intertrochanteric femur fracture

What does the study involve?
The main intervention is the common surgical treatment of intertrochanteric hip fractures in the elderly using a worldwide implant (single screw intramedullary nail) or a third-generation nail (InterTan) to investigate the differences in the main radiological measurements between these two at the 24 weeks follow-up. Intramedullary nailing for hip fractures is the standard care of treatment in our hospital and practically the patients would receive the same mode of treatment. Additionally, the researchers will compare the functional status of the patients using two disease specific scores as well as several other secondary objectives such as a comparison of surgical data, pain and patient-reported general health status before surgery and at 6-, 12- and 24-weeks after surgery.

What are the possible benefits and risks of participating?
The main benefits of the surgical treatment of intertrochanteric fractures in the elderly is the relief of pain, early mobilization, promotion of fracture healing and better quality of life and functional status. These benefits would be the same in the two groups of patients as similar treatment would be applied to both. Risks include the usual complications after hip fracture surgery such as an increased risk of death and illness and surgeon and implant-related complications.

Where is the study rub for?
Patras University Hospital (Greece)

When is the study starting and how long is it expected to run for?
October 2021 to May 2024

Who is funding the study?
Patras University and Patras University Hospital (Greece)

Who is the main contact?
Andreas Panagopoulos
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
52/15-2-2022

Study information

Scientific Title

Prospective, randomized, clinical study of single screw cephalomedullary nailing vs integrated dual interlocking screw fixation for unstable (AO/OTA A21-3) intertrochanteric fractures in patients >70 years old

Acronym
ProFNSD

Study objectives
The proposed single-center randomised controlled trial (RCT) has been designed to evaluate multiple clinical, radiological and quality of life parameters in an effort to investigate if there are any significant differences between the classic single-screw cephalomedullary nail (SSCN) and the new dual lag-screw nail (InterTan-IT). The main hypothesis is that the IT nail would provide better radiological outcomes and probably better clinical results than the SSCN nail.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/02/2022, Patras University Hospital Research Ethics Committee (Patras University Hospital, Papanikolaou 1, Rio-Patras, 26504, Greece; +30 (0)2613 604017; kefiap@1749.syzefxis.gov.gr), ref: ΑΠ 90-15/02/2022

Primary study design
Interventional

Study design
Prospective randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Interthcohanteric hip fractures in the elderly

Interventions
Patients will be randomised via a computerised generation system managed by the Orthopaedic Department of Patras University Hospital allocating patients to two study groups of equal weights using random block sizes of 3 and 6. Patients will be blinded to their allocation until the conclusion of the trial to reduce bias in patient-reported outcome measures. The statistician performing the analysis will also be blinded to the group allocation. Surgeons and researchers will not be blinded to allocation.

The clinical pathway for recruited patients remains unchanged from the usual routine of the hospital. Surgery is typically carried out within 24–48 hours, and no changes will be necessary to any part of the surgical episode with the exception of the individual device (SSCN or IT) used as directed by the randomization outcome. All fractures will be reduced in a fracture table and would be compressed proximally at the time of surgery, just prior to the nail insertion. A 130o nail will be used in all cases. Perioperative and postoperative management will remain unchanged from routine, including discharge timing and destination (nursing home or home). All patients will be mobilized with full weight-bearing as soon as possible after surgery.

This study will use two primary outcome measures: the Oxford Hip Score (OHS) and the Harris Hip Score (HHS). The minimum clinically important differences (MCIDs) for the HHS have been estimated between 7 and 10, whereas for the OHS between 5 and 7. The aim will be to recruit 78 patients in each group as this will provide sufficient participants to obtain a power of 90% for both primary outcome measures. With an allowance for 15% drop-out, the total number of patients required will be 194. If recruitment proves to be problematic during the course of the trial, then the target will be lowered and the more usual 80% power level will be considered sufficient. For this scenario, the total number of patients required will be 140 (including 15% for drop-out).

The primary outcome measure of device radiological failure is considered a binary outcome (device failed/did not fail). A binary logistic regression model will be performed to assess the association between the outcome of device failure and the predictor of device type (SSCN, Intertan). The complication rate of SSCN vs InterTan at 24 weeks post-operatively would be compared using a chi-squared (at the 5% level). The differences between HHS and OHS between groups will be assessed using an independent samples t-test at 24 weeks postoperatively at the 5% level. Test levels will be adjusted using the methods of Holm-Bonferroni to allow for multiple comparisons. A linear regression analysis will also be used to quantify the effects of the treatment groups on each of the primary outcome measures, after adjusting for the effects of a range of other important, potentially confounding, factors (e.g. age, gender) recorded for each patient.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Radiological measurements (cut-out, varus displacement, loss of reduction, malunion, nonunion) at the 24 weeks follow-up evaluation
2. Functional status assessed using patient-reported disease-specific scores (Harris Hip score HHS and Oxford hip score-OHS) at 6, 12 and 24 weeks follow up

Key secondary outcome(s)
1. Perioperative and intraoperative surgical data (delay for surgery, age-adjusted Carlson Comorbidity Index, operation time, fluoroscopy time and dosage, blood loss, length of hospital stay, prescription of pain-killers, osteoporosis assessment using postoperative DEXA of the unaffected hip, union time and intraoperative surgeon related complications, including lag screw malposition, propagation of the fracture, non-anatomical reduction, varus/valgus deformity, rotational deformity and tip-apex distance (TAD) using postoperative CT of the pelvis). All measurements are done during hospital stay except for union time which usually happens at 8-10 weeks post-surgery
2. Pain level measured using the visual analogue scale (VAS) Pain Score in the perioperative period and at 6, 12 and 24 weeks postoperatively
3. Patient-reported general health status measured using the SF-36 form, the EQ-5D-3L Questionnaire, the SARC-F Index and the Elderly Mobility Scale (EMS) prior to surgery and at 6-, 12- and 24-weeks post-surgery

Completion date
31/05/2024

Eligibility

Key inclusion criteria
1. Traumatic closed intertrochanteric femur fracture (A2 AO/OTA)
2. Patients aged over 70 years
3. Presentation to hospital within 7 days of injury
4. No concomitant injuries or prior operations to the unaffected hip

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
70 Years

Sex
All

Key exclusion criteria
1. Patients with concomitant injuries affecting treatment and rehabilitation of the affected limb
2. Patients with associated neurovascular injuries requiring immediate surgery
3. Patients with limited Greek proficiency including family members
4. Patients where consent is refused
5. Patients with severe dementia, non-ambulated and with severe associated diseases prohibiting operative intevention

Date of first enrolment
01/05/2022

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
Greece

Study participating centre
Patras University Hospital
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Sponsor information

Organisation
General University Hospital of Patras

ROR
https://ror.org/03c3d1v10

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Andreas Panagopoulos (anpanagop@upatras.gr)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/07/2023	31/07/2023	Yes	No