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A study on the reduction quality of intertrochanteric fractures following intramedullary fixation

Submission date
04/09/2017

Recruitment status
No longer recruiting

Registration date
21/09/2017

Overall study status
Completed

Last Edited
21/09/2017

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Intertrochanteric fractures (fractures that occur in the upper part of the thigh bone) are the most common fractures especially among elderly patients, accounting for 40 - 50% of all hip fractures. Early surgical intervention is usually the best strategy to fix this. The use of intramedullary fixation (the use of a locking rod) has increased in recent years due to its theoretic advantages and biomechanical superiority over extramedullary fixation (where the hip is stabilized on the outside of the thigh by puns or screws driven into the bone), especially in the unstable fracture patterns. However, complication rates of up to 20.5% have been reported using the intramedullary nail technique, and the two most common complications are excessive sliding of the cephalic nail and cut-out. The aim of this study is to examine medical reviews of patients to see if patietns with good reduction quality of the medial and anteromedial sustainable cortices had better clinical outcomes and lower complication rates.

Who can participate?
Adults aged 60 years and older who have fallen indoors or outdoors and suffered from the intertrochanteric fractures.

What does the study involve?
This is a chart review study. Participants who underwent internal fixation using a intramedullary nail are reviewed. They are are classified based on scans taken after the surgery. Their post-surgery scans and their three month follow up data are used to calculate their mobility and complications.
What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
Chinese PLA General Hospital (China)

When is the study starting and how long is it expected to run for?
January 2010 to December 2017

Who is funding the study?
Shoufazhuanxiang (China)

Who is the main contact?
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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Reduction quality of medial and anteromedial sustainable cortices influences the postoperative outcome following intramedullary fixation of 31-A2 intertrochanteric fractures: A retrospective study based on CT findings

Study objectives
Patients with good reduction quality of the medial and anteromedial sustainable cortices had better clinical outcomes and lower complication rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Chinese PLA General Hospital, 10/05/2009

Study design
Retrospective chart review

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
31-A2 intertrochanteric fractures: fracture extends over two or more levels of medial cortex

Interventions
This is a retrospective study. All patients underwent closed reduction and internal fixation (CRIF) with the intramedullary nail. The CT data of 43 patients with 31-A2 intertrochanteric fractures who underwent closed reduction and intramedullary internal fixation (CRIF) in the institution between January 2010 and December 2013 are retrospective analysed. All patients were classified to one of two groups based on the postoperative CT scans taken from the sagittal and coronal planes, respectively. The radiographic parameters of femoral neck-shaft angle (FNSA), sliding distance of the cephalic nail, femoral head height (FHH) and tip-cortex distance (TCD) on

the newly resliced coronal plane are measured. The immediate postoperative CT findings and the three-month follow-up data are both used for measuring the parameters and the changes are calculated. Clinical parameters like Harris hip score, timed “up & go” test and Parker-Palmer mobility score to evaluate the postoperative functional states and mobilisation levels at the final follow-up are measured. In addition to this, postoperative complications are also recorded. All the parameters between different groups are compared. The total duration of follow-up was six to 24 months.

Intervention Type
Device

Primary outcome measure
Radiographic parameters including Mean loss of the femoral neck-shaft angle (FNSA), sliding distance of cephal nail, change of Tip-cortex distance (TCD), change of Femoral head height (FHH) are measured using the Mimics software (Materialise, Leuven, Belgium) at three month follow up.

Secondary outcome measures
1. Hip function of patient was measured using Harris hip score (HHS) at the final follow-up
2. Time taken to rise from a sitting position and walk for 20 m is measured using timed “Up & Go” (TUG) test at the final follow-up
3. Functional level was also measured using the Parker-Palmer mobility score at the final follow-up
4. We defined loss of reduction as the loss of NSA greater than 10°, which is measured using the CT or radiographs
5. Cut-out is measured using the radiographs during the follow-up
6. Excessive sliding was defined as sliding distance ≥ 10 mm, which is measured using the CT or radiographs
7. Implant breakage is measured using the CT or radiographs during the follow-up

Overall study start date
01/01/2010

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Acute unilateral closed fractures
2. At least 3 consecutive (preoperative, within one-week postoperative, 3-months follow-up) CT examinations in addition to the X-ray radiographs
3. Patients aged 60 years and older
4. Follow-up periods of more than six months postoperatively
5. Nail shafts with the static distal locking

Participant type(s)
Patient

Age group

Senior

Sex
Both

Target number of participants
43

Key exclusion criteria
1. Pathological fractures such as carcinomas, metastases of the bone, primary malignant or benign tumors, and metabolic disorders
2. Mental disorders
3. Walking with assistive devices before the fractures
4. Fractures with associated neurovascular injuries
5. Pre-existing osteoarthritis or previous surgeries to the affected hip joints

Date of first enrolment
01/06/2011

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
China

Study participating centre
Chinese PLA General Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04gw3ra78

Funder(s)

Funder type
Charity

Funder Name
Shoufazhuanxiang

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Li (lijiantao618@163.com).

IPD sharing plan summary
Available on request