Fixation device related rotational influences in trochanteric femoral fractures:
a radio stereometric analysis of the DHS versus the gamma-nail

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON34783

Source
ToetsingOnline

Brief title
RSA study on trochanteric femoral fractures: DHS versus gamma-nail

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
proximal femur fracture, trochanteric fracture

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: bestaand fonds

Intervention

Keyword: femur, fixation technique, radio stereometry, trochanteric fracture

Outcome measures

Primary outcome

Rotation and translation as determined on RSA radiographs in relation to type

of implant used: intra-, or extra-medullary.

Secondary outcome

Micromotion in relation to the position of the femoral head screw and bone

density. Local adverse events (cut-out, implant failure)

Study description

Background summary

Several fixation devices have been developed for treatment of proximal femur fractures.
Still, treatment of these fractures suffers from relatively high complication rates.
For treatment of trochanteric fractures extramedullary sliding hip screw devices (e.g. DHS) and intramedullary nail fixations (e.g. Gamma-nail) are commonly used.
Both types of implant are related to complications like cut-out of the implant, nonunion and malunion.
Some of these complications may be accounted for by the induction of rotation and/or translation of the femoral head-trochanter fragment.

Study objective

To determine the amount of rotational instability in trochanteric femoral fractures, related to type of implant and fracture.
The primary goal is to evaluate differences in fracture micromotion (i.e.

translation and rotation) between different implants.
The secondary goal is to relate the micromotion to bone density (Dexa scans), the position of the femoral head screw(s), the type of implant used, and the type of fracture.

Study design

Sixty patients with an AO31-A2 type trochanteric fracture will be randomly allocated to treatment with either DHS or Gamma-nail. RSA radiographs are obtained postoperatively, on the first day, after 6 weeks, 4 months and one year. One dexa scan will be obtained within 6 weeks postoperatively.

Study burden and risks

The burden and risk associated with extra radiographs and the insertion of the tantalum beads of 0.5 mm diameter, used for RSA. Radiation risks are minimal and should be regarded in the context of the generally high age of this patient population. Normal X-ray protocol after a hip fracture is performed postoperatively, at 6 weeks, 4 months, and on indication at 1 years. Patients might benefit from the extended radiological examination and RSA during their follow up. In patients that are diagnosed with osteoporosis, treatment will be started.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age over 60 year
AO31-A2 type trochanteric fracture
informed consent

Exclusion criteria

age under 60 year
AO31-A1 or A3 type trochanteric fracture
no informed consent
severe arthritis of the involved hip
reumatoid arthritis
pathological fracture
pre-existent immobility

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	01-04-2010
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	osteosynthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-03-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	7771
CCMO	NL30533.058.09