Fixation device related rotational and translational influences in femoral neck fractures:
a radio stereometric analysis of fixation with the DHS versus three cannulated hip screws.

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To determine the amount of in fracture micromotion (i.e. rotation and translation) in femoral neck fractures, related to type of used implant: a DHS or 3 cannulated hip screws.The secondary objective is to relate the micromotion to bone density, and...

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

Summary

ID

NL-OMON34872

Source
ToetsingOnline

Brief title
RSA study in femoral neck fractures: DHS vs. 3 cannulated hip screws

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
Femoral neck fracture, hip fracture

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Femoral neck fractures, Fixation technique, Radiostereometry, Rotation

Outcome measures

Primary outcome

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

of implant used: DHS or 3 cannulated hip screws.

Secondary outcome

The amount of micromotion in relation to the position of the femoral head

screw(s). 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 femoral neck fractures there is a choice between fixation with preservation of the head or without preservation of the head. In case of preference for preservation of the head one can choose either a fixation with the sliding hip screw devices (e.g. Dynamic Hip Screw (DHS)) or with cannulated hip screws. Both implants are related to complications like cut-out of the femoral head screw(s), non-union and malunion. Some of these complications may be accounted for by the induction of rotation and translation of the femoral head fragment.

Study objective

To determine the amount of in fracture micromotion (i.e. rotation and

translation) in femoral neck fractures, related to type of used implant: a DHS or 3 cannulated hip screws.
The secondary objective is to relate the micromotion to bone density, and the position of the femoral head screw(s).

Study design

Sixty patients with non-displaced femoral neck fractures (Garden type 1 or 2) will be randomly allocated to treatment with either DHS or 3 cannulated hip screws. RSA radiographs are obtained postoperatively, on the first day, after 6 weeks, 4 months and one year. A dexa scan will be acquired within 6 weeks after fracture fixation.

Study burden and risks

The tantalum beads used with RSA are non-toxic and are not known to be associated to any burden or risk. Radiation risks (280 µSv in conventional hip X-rays versus 150 µSv in RSA X-rays) are minimal and should be regarded in the context of the generally high age of this patient population. Besides the RSA-measurements, all patients will be invited to a normal postoperative follow up protocol. Patients might benefit from the extended (radiological) examination during their follow up. A dexa scan is associated with 40 µSv. 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

- Aged over 60 years
- Impacted/non-displaced femoral neck fracture, Garden 1-2
- Informed consent

Exclusion criteria

- Aged under 60 years
- Displaced femoral neck fracture, Garden 3-4
- Severe arthritis of the involved hip
- Rheumatoid arthritis
- Pathological fracture
- Pre-existent immobility
- No informed consent

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):	14-04-2010
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Osteosynthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-04-2010
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	7857
CCMO	NL31156.058.10