RSA study on femoral neck fractures: DHS versus three cannulated hip screws.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29013

Source
Nationaal Trial Register

Health condition

Femoral fractures, Treatment
Femurfractuur, Therapie

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

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

1. The amount of micromotion in relation to the position of the femoral head screw(s);

2. Bone density;

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

Study description

Background summary

Rationale:

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.

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 and Study population:

Sixty patients, age >60 years, 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.

Intervention:

Micromotion across the fracture site (translation and rotation) determines stability of the performed osteosynthesis. Only if this micromotion is determined threedimensionally (3D), potential failure mechanisms can be analysed. Radiostereometric analysis (RSA) will be used to measure micromotion along the three orthogonal axes of the fracture fragments. RSA radiographs are obtained postoperatively, on the first day, after 6 weeks, 4 months and one

year. A 7-region dexa scan of both the fractured and non-fractured proximal femur and the lumbar spine will be acquired within 6 weeks after fracture fixation.

Main study parameters/endpoints:

Parameters: Demographical data, co-morbidity, rotation and translation as determined on RSA radiographs, type of implant: DHS or 3 cannulated hip screws, position of the femoral head screw(s), bone density and adverse events.

Primary endpoint: Rotation and translation as determined on RSA radiographs in relation to type of implant used: DHS or 3 cannulated hip screws.

Secondary endpoints: The amount of micromotion in relation to the position of the femoral head screw(s). Bone density. Local adverse events (cut-out, implant failure).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Study objective

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. 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

1. Fracture date;

2. Operation date;

3. RSA radiographs postoperatively, on the first day, after 6 weeks, 4 months and one year;

4. A 7-region dexa scan within 6 weeks after fracture fixation.

Intervention

Sixty patients, age >60 years, 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.

Micromotion across the fracture site (translation and rotation) determines stability of the performed osteosynthesis. Only if this micromotion is determined threedimensionally (3D), potential failure mechanisms can be analysed. Radiostereometric analysis (RSA) will be used to measure micromotion along the three orthogonal axes of the fracture fragments. RSA radiographs are obtained postoperatively, on the first day, after 6 weeks, 4 months and one year. A 7-region dexa scan of both the fractured and non-fractured proximal femur and the lumbar spine will be acquired within 6 weeks after fracture fixation.

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Eligibility criteria

Inclusion criteria

1. Aged over 60 years;

2. Impacted/non-displaced femoral neck fracture, Garden 1-2;

3. Informed consent.

Exclusion criteria

1. Aged under 60 years;

2. Displaced femoral neck fracture, Garden 3-4;

3. Severe arthritis of the involved hip;

4. Rheumatoid arthritis;

5. Pathological fracture;

6. Pre-existent immobility;

7. No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2010

Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion Date:	19-03-2010
Application type:	First submission

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
NTR-new	NL2129
NTR-old	NTR2253
Other	CME : P010.007
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A