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

Gepubliceerd: 19-03-2010 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29013

Bron
Nationaal Trial Register

Aandoening

Femoral fractures, Treatment
Femurfractuur, Therapie

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: Leiden University Medical Center (LUMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Erasmus Medical Center, Trauma Center ZWN, room Z-9.15,
P.O. Box 2040
I.B. Schipper
Rotterdam 3000 CA
The Netherlands
+31 (0)10 4635034

Wetenschappelijk

Erasmus Medical Center, Trauma Center ZWN, room Z-9.15,
P.O. Box 2040
I.B. Schipper
Rotterdam 3000 CA
The Netherlands
+31 (0)10 4635034

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Aged over 60 years;

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

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2010
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-03-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2129
NTR-old	NTR2253
Ander register	CME : P010.007
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A