Bone remodelling in femoral neck fractures treated with a dynamic hip screw.

Gepubliceerd: 22-05-2020 Laatst bijgewerkt: 13-12-2022

We expect an increased bone mineral density in the calcar region compared to the other ROI’s. Furthermore, we expect early detection of decreased mineral density of the femoral head in patients developing osteonecrosis of the femoral head.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20891

Bron
NTR

Verkorte titel
BMD after DHS

Aandoening

Hip fracture

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Unknown at this moment

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Changes in bone mineral density measured with Dual energy X-ray Absorptiometry in several regions of interest in the hip treated with a dynamic hip screw as a treatment for an intracapsular femoral neck fracture.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Intracapsular femoral neck fractures are common and are often treated with a dynamic hip screw in relatively young patients (<60 years). Complications as a cut-out or osteonecrosis of the femoral head after treatment with a dynamic hip screw still occur. The reason for these complications are possibly caused by bone remodeling around the dynamic hip screw and within the femoral head. Therefore, early detection of changes in bone density is needed. Literature regarding bone remodeling around the dynamic hip screw is scarce.

Objective: In this study we will monitor changes in bone mineral densities after intracapsular femoral neck fractures treated with a dynamic hip screw.

Study design: In this exploratory prospective study, we will include 25 patients with an intracapsular femoral neck fracture treated with a dynamic hip screw.

Study population: The study cohort consists of 25 patients who are treated with a dynamic hip screw after an intracapsular femoral neck fracture.

Intervention: Standardized measurements with Dual energy X-ray Absorptiometry will be done direct postoperatively and after 1, 3, 6 and 12 months postoperatively.

Main study parameters/endpoints: Changes in bone mineral density measured with Dual energy X-ray Absorptiometry in several regions of interest in the hip treated with a dynamic hip screw as a treatment for an intracapsular femoral neck fracture.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Four extra Dual energy X-ray Absorptiometry’s will be performed. Visits to the hospital are needed. A disadvantage is the extra, limited, radiation.

Doel van het onderzoek

We expect an increased bone mineral density in the calcar region compared to the other ROI’s. Furthermore, we expect early detection of decreased mineral density of the femoral head in patients developing osteonecrosis of the femoral head.

Onderzoeksopzet

15/07/2020: start inclusion
01/01/2021: end inclusion

01/01/2022: end follow-up
01/04/2022: submission article

Contactpersonen

Publiek

Rijnstate hospital
Peter Schmitz

0649786838

Wetenschappelijk

Rijnstate hospital
Peter Schmitz

0649786838

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients are eligible to participate if they are diagnosed with an intracapsular femoral neck fracture and are treated with a dynamic hip screw.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients are excluded from this study if the affected hip has a history of osteonecrosis of the femoral head, Perthes, osteoarthritis (Kellgren and Lawrence score III or IV) or a previous operation. Furthermore, patients that did not fully weight-bear the operated hip preoperatively will be excluded too.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	22-05-2020
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-05-2020
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	NL8649
Ander register	METC Rijnstate : 2020-1641

Resultaten