Intraprosthetic dislocation of the dual mobility total hip arthroplasty, does head size matter? A case series.

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A dual mobility cup with a small size head (22 mm) is more likely to result in intraprosthetic dislocation than a bigger size head (28 mm).

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20518

Bron
NTR

Verkorte titel
TBA

Aandoening

Total hip arthroplasty with the dual mobility cup for all pre-operative diagnosis.

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The frequencies of intraprosthetic dislocation in patients with a 22 mm and 28 mm head size

dual mobility cup in our study population.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The dual mobility (DM) cup is regularly used for total hip arthroplasty (THA) in both primary and revision surgery to create more stability in patients at risk for dislocation. This design consist of two articulations between three different components; a metallic acetabular shell, a mobile polyethylene liner, and a femoral head. Because this implant has a second articulation, DM THA's can suffer an implant specific complication better known as intraprosthetic dislocation (IPD), which occurs when the femoral head dislodges from the mobile polyethylene liner. IPD may occur at any time in follow up, for late IPD polyethylene wear seems to be the main cause. However, still little is known about risk factors for early IPD, considerations include head size.
Objective: The main objective is to investigate in an retrospective data analysis, if a small head size of 22 mm is more likely to dislocate than a bigger head size of 28 mm. Secondary to explore whether there is a difference in postoperative frequencies of intraprosthetic dislocation (IPD) between people who have received a DM cup as a primary THA or revision THA and to compare IPD rates to the rates of large articulation dislocations.
Study design: This is a single center retrospective cohort study using patient data from Rijnstate's electronic patient records.
Study population: All patients who have received a DM cup in the last ten years in Rijnstate hospital, with a minimum follow up of six weeks.
Main study parameters/endpoints: The frequencies of IPDs in patients with a 22 mm and 28 mm head size in our study population.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Because patients already received their treatment, and this study concerns retrospective cohort study using data from the electronic patient records, there is no patient related burden and risk associated with participation. No formal informed consent will be obtained because the sample size of this study is larger than 200 patients (conform our local hospital guidlines).

Doel van het onderzoek

A dual mobility cup with a small size head (22 mm) is more likely to result in intraprosthetic dislocation than a bigger size head (28 mm).

Onderzoeksopzet

January 2021 - May 2021; To identify all patients who have received a DM THA in the last ten years, a search on im-plant specific instruments registration will be conducted within Rijnstate's electronic patient records (HiX). Of the eligible patients the following data will collected: (1) age at surgery, (2) gender, (3) BMI, (4) ASA score, (5) reason for DM cup, (6)

cup & head size, (7) stem characteristics, (8) dislocation yes/no, (9) type of dislocation, (10) infection or fracture, (11) fol-low-up. For our primary outcome, it is necessary to know the cup & head size of the DM THA and whether or not it is dislocated. The other characteristics are needed for our secondary outcomes and to compare patient characteristics between the 22mm and 28mm groups. All individual data is extracted from Rijnstate's electronic patient records and placed in an anonymized data-file in 'Data Mangement' from my-researchmanger.com.
May 2021 - July 2021; export anonymized data-files from 'Data Mangement' to SPSS. Check for missing data. Statistical analysis; patient characteristics will be summarized descriptively in terms of frequencies (percentages of total) or means (standard deviations). Differences in the frequencies of dislocation rates between the two groups (22mm vs 28mm heads) will be analyzed using a Chi-square test. After the statistical analysis, the results are elaborated and a scientific article is written.

Onderzoeksproduct en/of interventie

Total hip arthroplasty with a dual mobility cup.

Contactpersonen

Publiek

Rijnstate Hospital
Ragna Jonker

+3 188 - 005 7744

Wetenschappelijk

Rijnstate Hospital
Ragna Jonker

+3 188 - 005 7744

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patiënts who have received a dual mobility total hip arthroplasty in the last ten years in our

hospital.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Lost in follow-up in the first six weeks after surgery.

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:	Anders
(Verwachte) startdatum:	04-01-2021
Aantal proefpersonen:	400
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-05-2021
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	NL9511
Ander register	LHC Rijnstate : 2020-1697

Resultaten