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

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20518

Source
NTR

Brief title
TBA

Health condition

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

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The frequencies of intraprosthetic dislocation in patients with a 22 mm and 28 mm head size dual mobility cup in our study population.

Secondary outcome

- The frequencies of large articulation dislocations.
- Pre-operative diagnosis for use of the dual mobility cup (distinguish; primary total hip arthroplasty and revision surgery).
- The complication rate of infection and fractures after a dual mobility total hip arthroplasty.

Study description

Background summary

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).

Study objective

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).

Study design

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.

Intervention

Total hip arthroplasty with a dual mobility cup.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	04-01-2021
Enrollment:	400
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-05-2021
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	NL9511
Other	LHC Rijnstate : 2020-1697

Study results