Migration in Total Hip Arthroplasty with a Cemented BiMobile cup: Better stability with more cement?

Published: 01-06-2018
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON56284

Source
ToetsingOnline

Brief title
Be-Mobile

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Total Hip Replacement; wear of hip joint

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: Link Hamburg

Intervention

Keyword: - Cemented Primary Total Hip Arthroplasty, - RSA, - Stability

Outcome measures

Primary outcome

Migration of the acetabular cup at two year postoperative, measured with RSA and CT. RSA x-rays will be collected at discharge, 6 weeks, 6 months, 1 year and 2 years after surgery. CT scans will be collected at discharge and 2 years after surgery.

Secondary outcome

Physical functioning, quality of life, pain and patient satisfaction will be scored with PROMs, consisting of: numeric rating scale (NRS) for pain in rest and during loading, Hip disability and Osteoarthritis Outcome Score Short Form (HOOS-PS), EQ-5D and an anchor question about general daily functioning. All PROMs will be collected prior to surgery, at 6 months, 1 year, 2 years and 5 years after surgery. Standard X-rays will be used for analysing the quality of the cement mantle (ie. cement cracks, cortical hypertrophy), component position, rate of radiolucent lines (>2mm), loosening and subsidence. All implant related (serious) adverse events including reoperations and survival of the THA (cup and stem component) will be collected up to 5 years after surgery.

Study description

Background summary

Total hip arthroplasty (THA) is a commonly performed surgery in patients with end-stage osteoarthritis (OA) of the hip. THA is known as a highly successful

procedure that improves the patients* physical functioning and reduces pain. Although it is known as a successful procedure, (recurrent) dislocation after THA is a major problem and results in a deterioration in quality of life. Dislocation after THA is the number one cause of early revision surgery. At one year follow-up 34,5% of all revisions were due to dislocation in the Netherlands.
Dual-Mobility (DM) acetabular cups should provide more stability and biomechanically reduce the risk of (early) dislocation. Potential disadvantages of DM cups are increased liner wear, psoas impingement and loosening. This might result in more revision surgery at mid- and longer term follow-up for the cemented cups. If the cemented fixation technique improves, this might diminish the disadvantages of more revisions due to loosening in cemented cups. High quality evidence guiding the best technique for cemented fixation is however lacking. There is evidence that an optimal reaming should be used, including the removal of the subchondral bone plate. The risk of implant loosening might be reduced by increasing the amount of cement used for cup fixation. It is currently unknown whether size of the implant, and thereby the amount of cement, affects stability and survival. To fill this gap in knowledge, this study will compare cup migration, as an indicator for loosening, in a new dual mobility cup (BiMobile, Waldemar Link GmbH & Co. KG, Hamburg, Germany), using a larger or smaller cup size (and thereby different amounts of cement: approximately 2mm or 4mm cement mantle). These results will also be compared with the Avantage cup (Zimmer), which is yet considered as a standard dual mobility cup in the Netherlands and Sweden. Migration will be measured with Rontgen Stereophotogrammetry Analysis (RSA), which is currently the gold standard for measuring early migration and predicting long term survival. A relatively new and less intensive way to measure migration of prostheses is the use of computer tomography (CT) scans, however there is still little scientific evidence on how accurately this can be done.This study therefore also measures the accuracy with which migration is measured, between CT scans and RSA.

Study objective

The main objective of this study is to compare the (early) migration of the cemented BiMobile cup at two year post-surgery between 2 different cup sizes after standard optimal reaming, and therefore adjusting the amount of cement into 2 or 4 millimeter, in patients with a primary cemented total hip arthroplasty. The results of the BiMobile cup will also be compared to the Avantage cup, which is placed with a standard cup size, resulting in a cement mantle of approximately 2mm.

Study design

A prospective single centre blinded randomised controlled trial, to compare the BiMobile cup with a standard amount of cement (standard cup size) after optimal reaming, with the BiMobile cup with a larger amount of cement (with a one size

smaller cup) after optimal reaming.
A third randomised group will receive the Avantage cup, with a standard amount of cement. All patients will be followed-up until 5 years after surgery. The study will be conducted in OLVG Amsterdam.

Intervention

Randomisation group A:
25 patients will receive a cemented THA with a BiMobile dual mobility cup, in a standard size after optimal reaming, resulting in a cement mantle of approximately 2mm.
Randomisation group B:
25 patients will receive a cemented THA with a BiMobile dual mobility cup, in one size smaller than standard after optimal reaming , resulting in a cement mantle of approximately 4mm.
Randomisation group C:
25 patients will receive a cemented THA with an Avantage dual mobility cup, in a standard size after optimal reaming, according to the investigator*s brochure, resulting in a cement mantle of approximately 2mm.

Study burden and risks

The risk for patients participating in this study is minimal, above the known risks for a total hip arthroplasty procedure. The devices that will be used, are CE marked and will be used according to it's labelling.
Known benefits of a total hip arthroplasty are reduced pain and an inproved range of motion of the hip. Although, there is no guarantee that patients will personally benefit from participation in this study.

Contacts

Public
OLVG

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Patients requiring a primary cemented THA.
- Male patients >=70 years old and female patients >=65 years old.
- Ability and willingness to follow instructions and to return for follow-up evaluations.
- The patient is able to understand the meaning of the study and is willing to sign informed consent.
- Understanding the Dutch language.

Exclusion criteria

- The subject is morbidly obese, defined as Body Mass Index (BMI) of > 40.
- Patient who is expected to need lower limb joint replacement for another joint within one year.
- The subject has a systemic or metabolic disorder leading to progressive bone deterioration.
- Patients having a deformity or disease located in other joints than the hip that needs surgery and is limiting their ability to walk.
- The subject has an active or suspected latent infection in or about the hip joint.
- The subject*s bone stock is compromised by disease or infection which cannot provide adequate support and/or fixation to the prosthesis.
- The patient is unable or unwilling to sign the informed consent specific to this study.
- Subject deemed unsuitable for participation in the study based on the investigator*s judgement.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-01-2019
Enrollment:	79
Type:	Actual

Medical products/devices used

Generic name:	Acetabulumcup
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-06-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	19-01-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-08-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL64196.100.17