Effectiveness of dual-mobility cups for preventing dislocation after primary total hip arthroplasty by a posterolateral approach and their cost-effectiveness compared to unipolar cups in elderly patients.

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

Summary

ID

NL-OMON54641

Source
ToetsingOnline

Brief title
REDEP

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Total hip replacement; hip dislocation

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedie
Source(s) of monetary or material Support: Van Rens Fonds

Intervention

Keyword: Dislocation, Dual Mobility cup, Primary Total Hip Arthroplasty

Outcome measures

Primary outcome

The number of dislocations, disregarding type of treatment (i.e. closed

repositioning or revision).

Secondary outcome

- Revision surgery of any component

- Patient Reported Outcome Measures (PROMs)

Standard following guidelines of the Dutch orthopaedic association (NOV.

Follow-up pre- operative, 3 months and 1 year postoperative. Additional for

this study: 2 years postoperative.

o HOOS-PS

o EQ-5D

o NRS-pain rest/weight bearing

o Anchor question about change in functioning

Added as extra question to the standard PROMs:

o Fear of hip dislocation on a 5 point Likert scale

* Added at all follow-up moments

o Healthcare and societal costs related to hip dislocation or surgery.

* Added at 3 months and 1 year postoperative.

Study description

Background summary

Dislocation is the leading reason for early revision surgery. To address the problem of dislocation, the dual-mobility (DM) cup was developed in France in the 1970*s. This cup should provide more stability and biomechanically reduce the risk of dislocation. In the Netherlands, most DM cups are placed in specific patients, e.g. with cognitive impairment and for revisions due to recurrent dislocations. Despite the increased and, in some countries, broad use of DM cups, high quality evidence of their (cost)effectiveness is lacking. This study aims to perform a trial to fill this gap in knowledge. Much of the information needed to judge the effectiveness of DM cups is already incorporated in the Dutch Arthroplasty Register (LROI). This register lends itself perfectly for an RCT towards this aim.

Study objective

The primary objective is to investigate whether there is a difference in the number of hip dislocations and revisions following primary total hip arthroplasty (THA), using the posterolateral approach, with a DM cup compared to a unipolar cup in elderly patients 1 year after surgery. The secondary objectives are: to investigate what the cost-effectiveness and cost-utility is of a DM cup compared to a unipolar cup at 1 year follow-up; to investigate whether there is a difference in the number of hip dislocations and revisions between a DM cup and a unipolar cup 2 years after surgery; to investigate whether there is a difference in patient reported outcomes between a DM cup compared to a unipolar cup 1 and 2 years after surgery; to compare the number of hip dislocations, revisions and PROM data between patients in the randomized DM group and patients in an observational cohort DM group. Finally, long-term survival of DM and unipolar cups will be evaluated based on revision and mortality data registered in the LROI.

Study design

Prospective multi-center nation wide, blinded RCT nested in the LROI.

Intervention

The intervention group receives a THA with a dual mobility cup, the control group receives a THA with a unipolar cup.

Study burden and risks

In addition to the benefits from regular care, the primary hip arthroplasty procedure, patients might benefit from randomization to receiving a DM cup. DM cups are designed to reduce the risk of hip dislocation, compared to a unipolar cup. Patients may undergo more thorough follow-up than non-study patients and may benefit from this increased surveillance compared with regular care. The only burden associated with study participation is the time needed to complete the cost questionnaires (all other outcomes are part of standard care).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Patients who are eligible for elective primary THA with a cemented cup, with

a 32mm or 36mm femoral head, for any indication
- Patients aged >= 70
- Using posterolateral surgical approach.
- Adequate comprehension of written and spoken Dutch

Exclusion criteria

- Patients unable to complete PROMs
- Patients with dementia, epilepsy*, spasticity*, mental retardation or alcoholism.
- Patients not eligible for either a unipolar or a DM cup, * these patients will be asked to participate in the non-randomized dual mobility cohort.

Study design

Design

Study phase:	4
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):	23-04-2019
Enrollment:	1000
Type:	Actual

Medical products/devices used

Generic name:	Acetebulum cup
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-10-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-03-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	23-07-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-06-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-04-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-11-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-11-2024
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	NL64819.100.18