Optimising recovery after cup revision or liner exchange- is the anterior approach superior to posterolateral?

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Does isolated cup revision surgery or liner exchange through the anterior approach result in increased functional status and higher patient satisfaction than through the posterolateral approach?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON52341

Source
ToetsingOnline

Brief title
Cuprevision or liner exchange approaches

Condition

- Bone and joint therapeutic procedures

Synonym
loosening/wear of acetabular cup or liner, revision of hip cup or liner

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: Reinier Haga Orthopedisch Centrum

Intervention

Keyword: Anterior approach, Cup revision or liner exchange, Functional recovery, Posterolateral approach

Outcome measures

Primary outcome

Difference in functional outcomes (30-second Chair Stand Test, 40m Fast Paced Walking Test, Stair Climb Test) between anterior and posterolateral approaches.

Secondary outcome

Modified Borg scale outcomes after functional tests, PROMS (NRS, Oxford Hip Score, HOOS-PS, EQ-5D-5L), inclination angle of the cup, complications at 30 days and 90 days after surgery.

Study description

Background summary

With increasing numbers of total hip arthroplasties performed each year, the incidence of problems related to loosening and wear of total hip arthroplasties is expected to also increase. While the anterior approach for primary total hip arthroplasty has demonstrated to result in a faster short-term recovery than the traditional posterolateral approach, this effect has not yet been investigated in revision surgery. Accelerating functional outcome may increase patient satisfaction and reduce healthcare costs.

Study objective

Does isolated cup revision surgery or liner exchange through the anterior approach result in increased functional status and higher patient satisfaction than through the posterolateral approach?

Study design

Prospective randomized controlled trial

Intervention

In one group the anterior approach will be used, in the other group the posterolateral approach.

Study burden and risks

Since both approached under study is are routine surgery, the additional burden of participation consists only of completing the functional assessment by the physiotherapist and completing a short extra questionnaire at routine care follow-up. There is no direct benefit for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >= 18
• On waiting list or scheduled for isolated cup revision surgery or liner exchange
• A good command of the Dutch language

Exclusion criteria

• Revision for confirmed or suspected infection
• Not suitable for both approaches under study, as judged by orthopaedic surgeon
• Cognitive impairment
• Unable to accurately follow instructions for study procedures / measurements, as judged by researcher and/or orthopaedic surgeon
• Unwilling to sign informed consent form

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-09-2022
Enrollment:	68
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	11-07-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-07-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL79031.058.21