Clinical comparison of the straight lateral approach and the anterior approach to the hip.

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

Summary

ID

NL-OMON44721

Source
ToetsingOnline

Brief title
Lateral vs. anterior approach

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
degenerative joint, osteoathritis

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Johnson & Johnson

Intervention

Keyword: anterior approach, cup positioning, hip, total hip replacement

Outcome measures

Primary outcome

The main study parameter of the study is the difference in recovery after a total hip arthroplasty with the anterior approach and a straight lateral approach. In the 3D CT reconstructions, the main study parameter is the difference in positioning the cup of a total hip arthoplasty after an anterior approach and a straight lateral approach.

Secondary outcome

not applicable

Study description

Background summary

The anterior approach to hip replacement surgery allows the surgeon to reach the hip joint from the front of the hip as opposed to the lateral (side) or the posterior (dorsal) approach. In this way, the hip can be replaced without detachment of any muscle from the pelvis or femur. In the present study, comparison is made between the anterior approach and the straight lateral approach. The focus will lie on the cup positioning, the user friendliness and the clinical results. In addition, we plan to develop a surgical strategy that alleviates one of the major complications of the straight lateral; abductor insufficiency.

Study objective

The objective of this project is to
1. increase accuracy and reproducibility of the most critical step in hip arthroplasty i.e. cup positioning;
2. to alleviate one of the major complications of the straight lateral approach, i.e. abductor insufficiency.
3. To assess the clinical results of the anterior approach compared to straight

lateral approach.

Study design

expertise-based randomized controlled intervention study

Intervention

One group receives a hip replacement through a straight lateral approach and one group through an anterior approach.

Study burden and risks

The patients included in the clinical trials will follow the normal rehabilitation protocol, with the exception that they will have to take some MRI scans and have to fill in several questionnaires. This will be done before or after a normal control appointment and will cost no more than 10 minutes each time. The risks involved with the intervention are no different from the normal risks involved. This study does not impose more, pre- and postoperative, risk to the patient than is seen in clinical performed hip replacement surgery. For the 3D CT reconstruction, patients will be measured before and after intervention (quantification of cup inclination with fluoroscopy and anteversion with goniometer). This will involve 2 extra visits to the hospital and a mild exposure to radiation (1.7 mSV).
The study will not provide personal benefits or increased, pre- and postoperative, risk to the participating patients but future patients might benefit from the results of the study performed.
Ultimately this will result in more insight in the anterior approach of the hip.

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

- Willing and able to participate in the study protocol
- Age > 18 years
- Diagnosed with hip problems which results in a hip replacement surgery.

Exclusion criteria

- Mental disabilities
- Language barrier
- Previous surgery to the hip or additional injury as in fractures
- Diabetes mellitus
- Preference towards surgeon or surgical method

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2011
Enrollment:	340
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	06-11-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	20-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	27-09-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL32278.098.10