The external hip rotator muscles after total hip replacement with the direct anterior approach
A pilot study

Published: 14-03-2016
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The purpose of our pilot study is to assess the status of the external rotator muscles and tendons of the hip after the DAA, with prospective Magnetic Resonance Imaging (MRI)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45014

Source
ToetsingOnline

Brief title
External hip rotator muscles after DAA

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
external rotators hip, short rotator muscles of the hip joint.

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: mede door ziekenhuis / onderzoeksbudget afdeling orthopedie en radiologie

Intervention

Keyword: anterior approach, hip, prosthesis, rotators

Outcome measures

Primary outcome

The main study parameter is assessing abnormalities of the external hip rotators on MRI by describing dehiscence of one or more tendons and grading muscle fatty atrophy.

Secondary outcome

To assess if the intraoperative estimated external rotator tendon release corresponds to postoperative abnormalities of the external rotators on MRI

To assess if there is a relation between external rotator abnormalities on MRI and postoperative hip function (including external rotation force) and pain symptoms (measured using questionnaires).

Study description

Background summary

The Direct Anterior Approach (DAA) is the standard approach for total hip replacement in our the Haga Hospital. This approach has rapidly gained popularity over the last decade because it is the approach that causes least muscle or tendon damage in comparison to other approaches to the hip. Nevertheless, for correct placement of the femur stem of the total hip prosthesis, soft tissue release at the proximal femur is needed. Ideally only the hip joint capsule is partially released from the greater trochanter, and this regrows in the first 6 weeks after the operation. But due to the close proximity of the capsule and the insertion of the five external hip rotator

tendons at the greater trochanter, some of these tendons may also be detached. When released, these tendons are not repaired at the end of the procedure. It is unknown whether these tendons reattach to their insertion site, whether and to which extent muscle atrophy results, nor whether such atrophy, if present, has functional consequences for the patient.

Study objective

The purpose of our pilot study is to assess the status of the external rotator muscles and tendons of the hip after the DAA, with prospective Magnetic Resonance Imaging (MRI)

Study design

Observational pilot study

Study burden and risks

Estimated MRI scanning time is 30 minutes. Possible risks for the participants are negligible, since MRI contains no radiation. Patients could get claustrophobic. When this occur the scan is stopped immediately and the patient will be excluded for the remaining study.

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 years
Scheduled for uncemented total hip replacement with Direct Anterior Approach
Informed consent

Exclusion criteria

Medical condition that is a contra-indication for MRI, e.g. pacemaker, ICD, cochlear implants or claustrofobia
Mental disabilities
Language barrier
Previous hip surgery
Hip replacement with another approach than the DAA (direct lateral or posterolateral approach)
Hip prosthesis for treatment of hip fracture
Cemented hip prosthesis
Osteoarthritis of contralateral hip
Osteoarthritis of the knee
Inability to flex hip and knee 90 degrees (for external rotation force measurement).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-08-2016
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO Date:	14-03-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-08-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-06-2017
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	NL53707.098.15