Gait Analysis in short and conventional stems in total hip arthroplasty in varus and valgus hips.

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

Summary

ID

NL-OMON48917

Source
ToetsingOnline

Brief title
GAIT trial

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
femoroacetabular offset, m. gluteus medius weakness

Research involving
Human

Sponsors and support

Primary sponsor: Stichting SCORE
Source(s) of monetary or material Support: de industrie,Mathys

Intervention

Keyword: functional recovery, gait pattern, short stem, total hip arthroplasty

Outcome measures

Primary outcome

The main parameter of this study will be the peak hip abduction moment, as the abductors of the hip will be most affected if the FAO is not restored properly (<5mm).

Secondary outcome

Kinematics: Hip abduction/adduction moment, hip range of motion in the frontal/sagittal plane, pelvic tilt range of motion, peak hip extension/flexion, peak hip internal/external rotation

Spatiotemperal variables: walking speed (at self-paced speed), stride length, cadence, step length, stance duration, single support, double support, cycle duration

Neuromuscular parameters: EMG of the hip abductors and muscle strength of the abductors.

Study description

Background summary

14-22% of the patients still have some complains after total hip arthroplasty. Restoration of femoro-acetabular offset (FAO) and center of rotation (COR) seems to be an important predictor of success for the clinical outcome of total hip arthroplasty. If not restored correctly, it might have influence on patient outcomes and survival outcome of the total hip arthroplasty. Especially in varus and valgus hips, the FAO can be difficult to restore. Nowadays there are different types of implants, each with their own advantages. One of the advantages of the short stem is its shape, which follows the medial side of the

femoral calcar, thus following the anatomical neckline of the femur better than a conventional stem could. Previous research by our own group showed that the short stem is more capable of restoring the FAO in varus and valgus hips than a conventional stem. The FAO has the most influence on the hip abduction moment, if the FAO is decreased more than 5mm this affect the lever of the hip abductors. This requires more strength from the abductor muscles, which generally cannot be produced and causes limping during gait. This study will help to see if there is a difference in gait after total hip replacement between a short stem and conventional stem.

Study objective

The main objective is to identify variations in the peak hip abduction moment after total hip arthroplasty with either the Optimys or the CBH in varus and valgus hips. Secondary objective are other kinematic and spatiotemporal parameters. Also, a patient reported outcome measurement score, HOOS, will be compared with gait pattern to see if there are clinical worse outcomes if gait is insufficient.

Study design

This is a case-matched observational pilot study. Gait analysis will be conducted in the innovative Gait Real-Time Analysis Interactive Lab (GRAIL) in the VU Medical Centre.

Study burden and risks

Patients will be seen one time at the VU medical centre for gait analysis. Patients will walk on a split-belt treadmill in the gait lab for 30 minutes, posing minimal risk. GRAIL is a safe and reliable system. Fall prevention will be provided with a safety vest and the treadmill will immediate stop after stumbling. Furthermore, the physical burden will be minimal; walking distance will not be longer than a patient can walk without experiencing pain/more pain than usual. An extra questionnaire (HOOS) will be given at the appointment, which cost an extra 10 minutes of the patients time.

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

* Participant in either the Optimys (NL47055.048.13) or CBH trial (NL48211.048.14
* Charnley A score
* Operating technique: direct lateral or anterolateral
* CCD-angle <120° or > 135°

Exclusion criteria

* Other conditions that influence walking patterns
* BMI>35
* Dysplasia or avascular necrosis of the hip which influences center of hip rotation
* Primary trauma, such as collum fracture, which could influence osteostomy cut of the femoral neck

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	26-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL62668.048.17

Study results

Date completed: 04-12-2019

Actual enrolment: 20