Functional recovery after hip replacement: A multivariate cohort study

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More insight into the recovery of function after HR over time, and in the relationships between function and its potential determinants in patients with HR, may lead to a better understanding of the problems in patients after HR, and help identify...

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON31216

Source
ToetsingOnline

Brief title
Functional recovery after hip replacement

Condition

- Joint disorders

Synonym
hip osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Biomet Nederland (een orthopaedische industrie),Biomet Nederland, Dordrecht, betaalt 50% van salaris en exploitatie

Intervention

Keyword: functional recovery, gait analysis, hip replacement, stability

Outcome measures

Primary outcome

Functional outcomes are:

-scores on SF36

-scores on WOMAC

-scores on an added question

-Harris hip score

-gait parameters

-scores on timed stair test

-measured maximum walking velocity

-self selected comfortable walking velocity.

Potential determinants that will be measured are:

-proprioception

-force

-inflammation mediators

-fear

-pain

-oxygen consumption.

Secondary outcome

See above

Study description

Background summary

Osteoarthritis (OA) is the most frequently observed joint disorder in seniors, and is often an indication for Hip Replacement (HR). In 1997, 112 out of 100.000 inhabitants of the Netherlands underwent HR, leading to a total of 17,400 hip replacements. This number is expected to increase in the coming years due to aging of the population. Survival rates (that is, time elapsed until a revision operation) for HR are high, and patients' reports suggest that patients have less pain and are usually satisfied. Despite these positive findings, the literature also reports that after one year most HR patients typically still show a deviant gait pattern, and walk slower than their healthy peers. Also other Activities of Daily Living, such as walking, stair climbing, rising from a low chair, entering or leaving a car, or a bathtub, may remain problematic for quite some time after HR, and patients report feeling "unstable" in the hip.

Study objective

More insight into the recovery of function after HR over time, and in the relationships between function and its potential determinants in patients with HR, may lead to a better understanding of the problems in patients after HR, and help identify aims for rehabilitation.
By assessing stability and variability during treadmill walking, and applying perturbations during gait on a treadmill, we will be able to gain insight into the stability in patients after HR.

Study design

The design is a multivariate cohort study of patients before and after HR, and a single measurement of healthy controls. At least 35 patients will be measured before the operation, after one, six, and 12, months. We will register co-morbidity and peri-operative complications. We will monitor inflammation mediators, hip abduction/flexion/extension force, hip proprioception in the frontal and the sagittal plane, oxygen cost of walking, and patient's self-reports (questionnaires on general health, osteoarthritis-related health, and fear of movement). All these factors are potential determinants of functional recovery. To monitor functional recovery itself, a simple ambulant test for functional ability (the timed stair test) will be administeredand, self reported measures (SF-36 and WOMAC) will be used, and walking kinematics will be recorded. In the gait analysis, we will pay special attention to the coordinative aspects of gait, and the stability during gait.

Study burden and risks

The major "price" the participant pays is the loss of time: 4 visits to the VUmc, which, all in all, will each take half a day. Patients are encouraged to bring relevant others. If they do, both will be offered lunch, drinks, etc. Participants usually find our research "interesting", and tend to enjoy their "day off" in our lab. Moreover, they find it comforting that other people (among whom an orthopaedic surgeon at an academic institution) meet with them, and examine them.
Technically, the risks are very low. Two researchers (one of which at least a physical therapist) will be present during all measurement sessions, and during treadmill sessions, participants are secured in a harness so that falling is impossible. Therefore, the study does not impose a great risk on injury, dislocation of the prostheses, or any other medical inconvenience.

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 between 50 and 70 (inclusive)
osteoarthritis of the hip
indication for hip replacement

Exclusion criteria

replacement of the other hip or other lower extremity joints (before, or scheduled, or to be scheduled)
revision operation
any conditions, other than osteoarthritis of the hip, that interfere with gait (such as neurological, skeleton-muscular, or obstetric disorders)
any conditions that render the patient too unfit to be tested (such as pulmonary and/or cardiac disorders)
any conditions that render the patient unable to understand or adhere to the protocol (such as cognitive, visual and/or language problems, or hand problems, that render the patient unfit to fill-in the questionnaires)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

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	NL17223.029.07