Clinical study on total hip arthroplasty patients with instrumented shoes

Published: 10-06-2011
Last updated: 29-04-2024

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

Summary

ID

NL-OMON37965

Source
ToetsingOnline

Brief title
Using instrumented shoes in THA patients.

Condition

- Joint disorders

Synonym
Osteoarthritis in the hip/Wear and tear of hipjoint

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ambulatory measurements, Instrumented force shoes, Rehabilitation, Total Hip Arthroplasty

Outcome measures

Primary outcome

The main study parameter will be the gait velocity calculated through the IFS

(product of the stride length and the stride frequency).

Secondary outcome

Stride length and stride frequency separately as well as the symmetry in ground

reaction force will be the secondary parameters. In addition, the IFS

parameters correlated to the gait velocity (assessed independently from the

IFS) and the outcome of the questionnaires (HHS, WOMAC-FC and VAS) are

secondary parameters.

Study description

Background summary

Total hip arthroplasty (THA) is a successful surgical procedure to treat orthopedic osteoarthritis. Studying the differences in movement during various activities of daily living before and after total hip replacement is important for the follow up of the patients. Clinicians use different questionnaires filled out by patients that have been standardized to assess and compare the patient's pain and functional capacity. These questionnaires as well as gait velocity show significant improvement after THA (Vissers et al, 2011). This clinical evaluation is not based on objective physical measurements and does not provide information about the movement patterns underlying the functional capacity. This information is however clinically important and can currently only be obtained in a fully equipped gait laboratory. Instrumented force shoes (IFS) can quantify gait velocity, step time and length, ground reaction forces and the position of the center of pressure during walking and therefore can be used to quantify the gait pattern in an outpatient setting.

Study objective

The first aim of this study is to investigate whether the IFS is a sufficiently sensitive instrument to show differences in mobility performance between before and after THA. The second objective is to investigate how mobility characteristics, as measured with the IFS, relate to global functional parameters gait velocity and questionnaire outcomes (HHS, WOMAC-FC).

Study design

Prospective cohort study with two measurement sessions: pre-operative and 6-8 months post-operative.
Patients undergoing THA will be measured before and 6-8 months after the operation. Both measurements include 3 functional mobility tasks while the subject is wearing instrumented force shoes (IFS). In the first task, the subject is instructed to walk several times through the corridor from the beginning to the predefined endpoint. Subsequently, the subject is asked to stand and sit in a chair with arms folded across the chest 5 consecutive times. The third task is to ascend and descend a total of 5 steps of a stair. Before and after each measurement a Visual Analogue Scale (VAS) will be used to score pain in the hip. Besides the VAS, after each measurement the Harris Hip Score (HHS) and the Functional capacity part of the Traditional Western Ontario and McMaster Universities osteoarthritis index (WOMAC-FC) will be administered.

Study burden and risks

There is no risk associated with participating in the measurments. Each measurement will take about 40 minutes and will be planned during a regular clinic visit. There is no direct benefit for the patient. However, future patients shall benefit from the results because functional mobility performance before/after THA can be assessed quantitatively in a clinical setting, which can help the orthopedic surgeon in the future to evaluate the effect of THA.

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 80 years.
•Primary, unilateral, osteoarthritis of the hip.
•Patients should be selected for a primary THA and undergo the operation within the next 4 months.

Exclusion criteria

•Have bilateral THA.
•Have any kind of leg arthroplasties.
•Have rheumatoid arthritis
•Have any neurological disorder.
•Not able to perform the tasks because of pain or impairment.
•Suffering also from other degenerative diseases.
•Develop a bilateral disease.
•Revision/re-operations of primary hip prosthesis
•Unable to understand instructions or the questionnaire

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):	08-07-2011
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	10-06-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
Other	Candidate number 9442
CCMO	NL36629.044.11