

Using instrumented shoes in THA patients.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29531

Source

NTR

Brief title

IFS THA

Health condition

Total Hip Arthroplasty
Instrumented force shoes
Ambulatory measurements
Rehabilitation

Sponsors and support

Primary sponsor: University of Twente

Source(s) of monetary or material Support: University of Twente

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The second objective is to compare the IFS parameters to the gait velocity (assessed independently from the IFS) and questionnaire outcomes.

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. Instrumented force shoes (IFS) can be used to quantify the movement patterns in an outpatient setting. 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. Prospective cohort study with two measurement sessions: pre-operative and 6-8 months post-operative. In total 25 patients with primary osteoarthritis of the hip selected for a primary THA will perform 3 functional mobility tasks, walking, sit-to-stand, stand-to-sit, stairs ascend and stairs descend in both measurements.

Study objective

The aim of this first study is to evaluate the use of the IFS for quantitative assessment of mobility performance in comparison with gait velocity and questionnaires already validated and studied in patients before and after THA in an outpatient clinical setting. If the IFS parameters appear to be sensitive, 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.

Study design

Patients undergoing THA will be measured before and 6-8 months after the operation.

Intervention

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.

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Eligibility criteria

Inclusion criteria

1. Age between 50 and 80 years;
2. Primary, unilateral, osteoarthritis of the hip;
3. Patients should be selected for a primary THA and undergo the operation within the next 4 months.

Exclusion criteria

1. Have bilateral THA;
2. Have any kind of leg arthroplasties;
3. Have rheumatoid arthritis;
4. Have any neurological disorder;
5. Not able to perform the tasks because of pain or impairment;

6. Suffering also from other degenerative diseases;
7. Develop a bilateral disease;
8. Revision/re-operations of primary hip prosthesis;
9. Unable to understand instructions or the questionnaire.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2011
Enrollment:	25
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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
NTR-new	NL2764
NTR-old	NTR2903
Other	METC TWENTE : P11-17
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A