Using instrumented shoes in THA patients.

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29531

Bron
Nationaal Trial Register

Verkorte titel
IFS THA

Aandoening

Total Hip Arthroplasty
Instrumented force shoes
Ambulatory measurements
Rehabilitation

Ondersteuning

Primaire sponsor: University of Twente
Overige ondersteuning: University of Twente

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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, stad-to-sit, stairs ascend and stairs descend in both measurements.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2011
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2764
NTR-old	NTR2903
Ander register	METC TWENTE : P11-17
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A