SensiStep Study
Resumption of weight bearing among total hip prosthesis patients; a pilot study

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This study aims to improve the first phase of rehabilitation after THA. The primary objective is to analyse the effect of feedback to the patients. The secondary objective is to quantify the weight bearing in the early phase after THA surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON41048

Source
ToetsingOnline

Brief title
SensiStep Study in Total Hips

Condition

- Bone disorders (excl congenital and fractures)
- Bone and joint therapeutic procedures

Synonym
arthrosis of the hip joint, coxarthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Monitoring, SensiStep, Total Hip Arthroplasty, Weight Bearing

Outcome measures

Primary outcome

The primary outcome parameters are generated by the SensiStep system:

- Loading rate

- The number of steps per time unit

- The number of Periods of Dynamic Loading, PDL

Secondary outcome

N.A.

Study description

Background summary

Total Hip Arthroplasty (THA) is a common surgical procedure for treatment of coxarthrosis. Rehabilitation after such a procedure is hampered by the absence of good quality data on the rehabilitation process, in other words, there is no instrument available to measure the progress of rehabilitation. The SensiStep system is an ambulant monitoring system that is used to register pressure data under the heel. The aim of this pilot study is to detect the postoperative weight bearing after THA. Using the feedback of the data generated by the SensiStep system to the patient, the changes in the postoperative weight bearing will be analyzed. These data will be used to calculate the sample size for a bigger RCT, but as no such data are yet available, this pilot study is a first step. Results of this study could affect other patient groups after elective orthopedic surgery, as well as after fractures of the lower extremity.

Study objective

This study aims to improve the first phase of rehabilitation after THA. The primary objective is to analyse the effect of feedback to the patients. The secondary objective is to quantify the weight bearing in the early phase after THA surgery.

Study design

In this randomised study, all patients will be monitored after THA using the SensiStep system. Randomisation will determine which patients will recieve feedback during weight bearing. Monitoring will take place at day 1,2,3, and 4 postoperative during the admission, and at weeks 6 and 12 in the outpatient clinic.

Intervention

Weight bearing is registered in both study groups with the SensiStep system. In the intervention group, direct feedback will be given during the weight bearing using a wrist device. Using this device, patients can adjust the amount of weight bearing.

Study burden and risks

During the regular practice sessions with the physical therapists, registration of pressure under the sole will take place using the SensiStep system. This will take place during the admission in the hospital at day 1,2,3 and 4 postoperative, and at weeks 6 and 12. There are no additional questionnaires or measurements taken other than the Harris Hip Score, which is part of the operation protocol. A risk analysis has shown no additional risk for the patients by using the SensiStep system. Benefits are not expected within the scope of this study.

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 60 and 85 years
Elective surgical total hip prosthesis for coxarthrosis
Postoperative full weight bearing

Exclusion criteria

Lack of informed consent
Cognitive impairment, either pre-existent or occuring in the first day or days after surgery
Insufficient knowledge of Dutch language
Pre-opeartive comorbidity influencing the mobility other than coxarthrosis (e.g. confined to wheelchair, walking distance < 10 meters)
Complications during surgery
Weight more than 120 kg
Revision surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2015
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	SensiStep
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-01-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL49553.041.14