Possibilities of a muscle transfer to replace absent hip abductors after Total Hip Arthroplasty (THA)

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

Summary

ID

NL-OMON31155

Source
ToetsingOnline

Brief title
Muscle transfer after THA

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
loss of function of the m. gluteus medius (middelste bilspier)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: hip, muscle, total hip arthroplasty, transfer

Outcome measures

Primary outcome

The primary study outcome is the difference between hip abduction strengths between healthy people, people with a hip abduction deficiency as a result of a total hip arthroplasty, and people with a hip abduction deficiency as a result of a total hip arthroplasty with a simulated muscle transposition.

Secondary outcome

not applicable

Study description

Background summary

A total hip prosthesis for a coxarthrose improves for almost all patients the quality of life. A small group however, develops a gait disorder (Trendelenburg gait) after the operation, due to a hip abduction deficiency (especially the m. gluteus medius). This results in a instable hip and a lurching gait. Currently there is no surgical treatment possible for these patients. This study investigates the possibility of a muscle transposition so as to restore hip abduction strength, resulting in a stabile hip and a normal gait pattern.

Study objective

The primary goal of this research is to study the effect of several simulated muscle transpositions in patients with a hip abduction weakness, caused by a total hip arthroplasty. With the use of a musculoskeletal model of the lower extremities, it is possible to simulate muscle transpositions. The effect of each simulated muscle transposition can be compared with each other, so as to determine the muscle transposition which restores hip abduction strength the best, without compromising other strengths (like flexion and rotation).

Study design

This study needs data from static trials, gait trials and force measurements of 5 healthy and 10 patients with a functional hip abduction weakness as a result of a total hip arthroplasty. The measurements are at the gait laboratory of Roesingh Research and Development (RRD). During the measurements EMG signals of 6 leg muscles, VICON signals, force plate signals and maximal isometric abduction and flexion forces are registered.

Study burden and risks

The measurements take in total approximately 3 hours. The risk for the subjects is small, since only static, gait and force measurements are performed. The risk for a subject of falling is not greater than it is during daily walking. During the force measurements, no external forces are applied on the subject. Only forces the patient generates are measured, making the risks small. To reduce the risks even further, an experienced revalidation-physician or physiotherapist is present during the measurements.

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

patients:
- with a functional hip abduction deficiency, as a result of a total hip arthroplasty
- who are 18 years of age or older
- with a unilateral hip abduction deficiency
- patient is able to walk independantly
- with sufficient cognitive capabilities;Healthy people:
- who are 18 years of age or older
- with sufficient cognitive capabilities

Exclusion criteria

Patients:
- who have other functional limitations which influence their gait pattern (like knee or ankle injuries);Healthy people:
- who have limitations which influences their gait pattern

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):	01-10-2007
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	01-11-2007
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL19065.075.07