The effects of additional intensive preoperative strength training on preoperative strength, voluntary activation and functional tasks, and postoperative recovery for patients awaiting total knee arthroplasty

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON35093

Source
ToetsingOnline

Brief title
PITSTOP

Condition

- Joint disorders

Synonym
osteoarthritis

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Manchester Metropolitan University

Intervention

Keyword: Osteoarthritis, Rehabilitation, Strength training, Total knee arthroplasty

Outcome measures

Primary outcome

Knee extension force of both legs

voluntary activation of the quadriceps (with use of electro stimulation)

Secondary outcome

Cross sectional area of the quadriceps

Time for the *five times sit to stand test

Distance walked during the *six minute walk test*

Time for the stair climb test

Range of motion of the knee

Time for a balance test

WOMAC

VAS pain

Study description

Background summary

95% of the patients undergoing total knee arthroplasty are diagnosed with osteoarthritis. Osteoarthritis is a joint disease which is characterized by pain, loss of force and problems during activities of daily life. This can

result in reduced social participation and quality of life. Current advice on preoperative training is very diverse. Some hospitals advise patient to consult a physiotherapist before surgery, while others do not. Between physiotherapists there are large differences in treatment. While some only train walking with aids, others perform intensive strength training. Because there is evidence that intensive strength training is beneficial post surgery, our hypothesis is that preoperative training also leads to increases in muscle strength, voluntary activation, and physical functioning. Further we expect to find indications that positive preoperative effects promote postoperative recovery. This study can help to shorten recovery and increase the quality of life for patients undergoing total knee arthroplasty.

Study objective

The primary goal of the study is to investigate whether additional intensive strength training can lead to increases in strength and voluntary activation and pysical functioning before surgery. Further, it is a goal to study if there are indications that preoperative strength, activation and functioning are related to recovery post surgery.

Study design

Randomized clinical trial

Intervention

The intervention will be a six week intensive strength training program pre surgery. The training will be performed twice a week. See the protocol for further details.

Study burden and risks

Subjects will participate in research project executing a 6 week strength training program training 2 days/week. Measurements will be performed at 4 different time slots including tests that assess neuromuscular function and functional tasks (duration about 1.5 hours). Subject may experience some discomfort during electrical stimulation and/or muscle soreness after muscle tests. Furthermore, the risks during training and testing sessions are relatively low because of thorough screening prior to participation, use of skilled and licensed therapists and safety precautions throughout training and testing. The expected beneficial training effects in combination with the limited risks would justify execution of the proposed 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

Awaiting unilateral total knee arthroplasty
Age>55

Exclusion criteria

contraindications for training the lower limbs
ASA>2 (American Society of Anesthesiologists)
severe cognitive and/or communicative problems, preventing ability to follow verbal instructions
other problems that would limit the ability to perform the requested tasks
contra-indications for electrical stimulation (unstable epilepsy, cancer, skin abnormalities,

pacemaker).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2010
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	07-07-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL30715.029.10

Study results

Date completed:	14-03-2012
Actual enrolment:	22