Preoperative physical therapeutic intervention for high-risk patients who are scheduled for elective total hip arthroplasty

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Primary Objective: The primary objective is to investigate the feasibility of a short-term preoperative physical therapeutic intervention for frail elderly patients, who have a higher risk on postoperative complications or a delayed recovery, after...

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

Summary

ID

NL-OMON30614

Source
ToetsingOnline

Brief title
Profyth

Condition

- Joint disorders

Synonym
preoperative functional capacity / physical condition before surgery

Research involving
Human

Sponsors and support

Primary sponsor: Gelderse Vallei

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Exercise, Preoperative, Therapeutic Intervention, Total Hip

Outcome measures

Primary outcome

Feasibility is the main study parameter in this study. Patients satisfaction with and adherence to the training will be assessed and also occurrence of adverse events will be monitored. Also the patients satisfaction towards the questionnaires and physical tests is assessed.

Secondary outcome

- Aerobe Capacity (PWC-170)
- Muscle strength of the lower limbs (1-RM/Chair Rise Time)
- Pain and function of the hip joint (HOOS)
- Quality of Life (SF-36)
- Functional mobility (Timed Up and Go)
- Patient Specifieke Klachten (PSK)
- Self reported activities (LAPAQ and Pedometer)
- Functional mobility (time to go up and go)
- Walking capacity (six minute walk test)

Study description

Background summary

Total hip arthroplasty (THA) as final treatment in end-stage osteoarthritis has become more and more accepted and used over the last two decades. Though most

patients recover significantly after a THA, others experience fewer benefits. Often, the persons that benefit the most from THA are in general preoperative in a better functional status than those who benefit less. Numerous preoperative factors, such as negative expectations, functional status and pain can negatively affect the outcome of a THA.
It seems rational, that improving the preoperative functional status would also improve the outcome of the THA. The underlying notion is: *the better patients enter the hospital, the better they will leave*. Therefore, we hypothesize that therapeutic training of the aerobic capacity, muscle strength and functional capacity will lead to a faster hospital admission after the total hip arthroplasty. To gain more insight on the effects of a therapeutic intervention on the postoperative recovery in frail elderly patients who were scheduled for elective THA, a full randomized controlled trial (RCT) has to be performed. But before embarking on a proper RCT, we will first perform a pilot study to test the feasibility of the approach and to help clarify decisions about operational issues and procedures.

Study objective

Primary Objective:
The primary objective is to investigate the feasibility of a short-term preoperative physical therapeutic intervention for frail elderly patients, who have a higher risk on postoperative complications or a delayed recovery, after elective total hip arthroplasty.

Secondary Objective(s):
The secondary objectives are to investigate the effect of short-term high-intensity physical training program for frail elderly patients who are scheduled for elective total hip arthroplasty on (i) the preoperative aerobic and functional capacity and muscle strength and (ii) on the postoperative health status and the functional recovery.

Study design

Single blind randomized controlled pilot trial.

Intervention

The intervention group receives a preoperative patient-tailored therapeutic physical exercise program for 3-6 weeks, 2-3 times a week. The patients recieve a home-based exerciseprogram for minimal 30 minutes on non-trainingdays. The training is directed at improving the aerobic capacity, the muscle strength of the lower limb muscles and the functional capacity.

Study burden and risks

Time investment for the patients
- screening at the onset of the study and 2 days before surgery, 90 minutes each time (intervention and control group)
- training 2-3 times a week during 60 minutes for 3-6 weeks in the outpatient department of the hospital
- training at home for minimal 30 minutes each day, on the days the patients do not train at the hospital (intervention group)

Nature of burden
- high intensity physical exertion (intervention group).
- completing a questionnaire (intervention and control group).
- performance of a simple functional test in postoperative period (intervention and control group).

Risks
Elderly patients can safely tolerate high-intensity resistance training programs. The risk is comparable with the normal risk associated with physical exertion.

Contacts

Public
Gelderse Vallei

Willy Brandtlaan 10
6716 RP Ede
Nederland
Scientific
Gelderse Vallei

Willy Brandtlaan 10
6716 RP Ede
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

a. Scheduled for elective total hip arthroplasty (minimum waiting period of 3 weeks)
b. Osteoarthritis is the motive for the THA.
c. First surgical intervention of this pathology.
d. High risk for postoperative functional decline.
e. Age >= 70 years.

Exclusion criteria

a. Unable to understand Dutch
b. Severe heartdisease

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2007
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	29-05-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-08-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-05-2009
Application type:	Amendment
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	NL15874.041.07