Preoperative high-intensity physical training for elderly patients who are scheduled for elective abdominal oncological surgery

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

Summary

ID

NL-OMON29826

Source
ToetsingOnline

Brief title
Profyt

Condition

- Muscle disorders

Synonym
preoperative functional capacity / physical condition before surgery

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: Aged, Exercise, Physical fitness, Preoperative care

Outcome measures

Primary outcome

Maximal aerobic capacity (VO2max)

Strength lower leg extensors and inspiratory muscles.

Patients satisfaction with and adherence to the training.

Secondary outcome

Hand grip strength

Maximal Inspiratory Pressure (MIP)

Endurance inspiratory muscles

Self reported activities (LAPAQ)

Functional mobility (time to go up and go)

Walking time (pedometer)

Quality of live (EORTC QLQ-C30 questionnaire)

Study description

Background summary

Peri-operative care is extending to the preoperative period. The underlying notion is: the better patients enter the hospital, the better they will leave. Functional capacity forms part of the preoperative risk profile, predicting the postoperative course. Especially elderly patients* lack of functional capacity can lead to a postoperative functional decline causing postoperative complications and an increase of length of stay. Within the preoperative framework, maximal aerobic capacity and muscle strength of the inspiratory and lower leg muscles are important determinants of functional capacity.

Preoperative training of patients who are scheduled for elective oncological surgery can improve these determinants prior to surgery. There is evidence that long-term training of the elderly has a positive effect on maximal aerobic capacity and muscle strength. However, the effect of a high-intensity training of 2-4 weeks (length of time on the waiting list) needs further investigation.

Study objective

The objective of this pilot study is to investigate the feasibility and effect of a high-intensity physical training program for elderly patients who are scheduled for abdominal oncological surgery on the preoperative maximal aerobic capacity and muscle strength.

Study design

A single blind randomized controlled trial.

Intervention

The intervention consists of a preoperative patient-tailored physical training program to improve the functional capacity. The control group receives a home based exercise program. The intervention group receives an additional high-intensity training program, three times a week in the outpatient department of the hospital. The training is directed at improving the exercise capacity, the function of the inspiratory muscles and the muscle strength of the lower limb muscles.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness

Time investment for the patients
- screening at the onset of the study and 2 days before surgery, 60 minutes each time (intervention and control group)
- training 2 - 3 times a week during 60 minutes for 2-4 weeks in the outpatient department of the hospital (intervention group)
- training at home on the days the patients don*t train in the outpatient department of the hospital for 30 minutes each day (intervention group)
- training at home for 30 minutes each day (control group)

Nature of burden
- high intensity physical exertion (intervention group).
- physical exertion (control group).
- completing a questionnaire (intervention and control group).
- performance of a simple functional test in postoperative period (30 seconds,

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
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584CX Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584CX Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Elective colon surgery (waiting period for a minimum of 2 weeks)
2. Age 60 >= years
3. Adequate cognitive functioning

Exclusion criteria

1. Heart disease that prohibit or impede exercise
2. Severe systemic illness
3. Recent embolism
4. Thrombophlebitis
5. Uncontrolled diabetes
6. Severe orthopedic conditions that prohibit or impede exercise
7. Dependent on a wheelchair

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):	05-10-2006
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	05-09-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	20-02-2007
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	NL13239.041.06