A preoperative program to promote peri- and postoperative health in patients undergoing thoracic aortic surgery: a randomized controlled trial.

Published: 25-01-2021
Last updated: 15-05-2024

To compare the effects of a preoperative PA program in addition to usual care versus usual care only on the change in SB from baseline (T0) to the end of the preoperative (intervention) period (T1) in patients with TAD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Deliria (incl confusion)
Study type	Interventional

Summary

ID

NL-OMON50977

Source
ToetsingOnline

Brief title
MAS study

Condition

- Deliria (incl confusion)
- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
thoracic aortic disease; thoracic aortic aneurysm

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Handgrip training, Physical activity intervention, Sedentary behaviour, Thoracic aortic surgery

Outcome measures

Primary outcome

The primary study parameter is the difference between the control group and intervention group in the change in SB (h/day) from baseline (T0) to preoperative follow-up (T1). SB will be assessed using the validated ActivPAL micro (ActivPAL micro, PAL technologies, Glasgow, United Kingdom) activity monitor.

Secondary outcome

The secondary study parameters are the differences between the control group and intervention group in changes in:

* SB from baseline (T0) to postoperative follow-ups (T3 and T4);

* PA levels (h/day walking and stepping) from baseline (T0) to pre- and postoperative follow-ups (T1, T3 and T4);

* BP levels from baseline (T0) to pre- (T1) and postoperative follow-up (T4);

* maximal handgrip strength from baseline (T0) to pre- and postoperative follow-ups (T1, T3 and T4).

* cerebral perfusion levels from baseline (T0) to intra- and postoperative follow-up (T2 and T4);

* cognitive function from baseline (T0) to postoperative follow-up (T4);

* functional exercise capacity from baseline (T0) to pre- and postoperative

follow-up (T1 and T4);

* anxiety for performing exercise and/or PA from baseline (T0) to pre- and

postoperative follow-up (T1 and T4).

Study description

Background summary

Most patients with thoracic aortic disease (TAD), mostly involving aneurysms or dissections, ultimately undergo thoracic aortic surgery (TAS) to prevent fatal rupture. TAS involves complex and intensive procedures, thus represents a significant perturbation to the human body, in particular to the brain. Although cerebral perfusion strategies can protect the brain during TAS, perioperative cerebral (hypo-)perfusion may relate to high rates of postoperative neurological deficits.
TAD patients are advised to modify their lifestyle, e.g. by quitting smoking and controlling blood pressure. High intensity levels of physical activity (PA) are discouraged, as sudden hemodynamic changes (e.g. increased blood pressure) are unfavourable. However, low intensity levels of PA (e.g. walking or standing) are considered to be safe, and, moreover, are known to have many beneficial effects on cardiovascular and general, whereas sedentary behaviour (SB, i.e. physical inactivity) is the most important modifiable risk factor for cardiovascular disease. Moreover, reducing SB has been shown to enhance cerebral perfusion. With regard to TAD, in mice with Marfan syndrome, beneficial effects of low intensity PA were found on the thoracic aortic diameter and aortic wall strength. Therefore, replacing SB by low intensity levels of PA in patients with TAD is a promising strategy to improve perioperative cardio- and cerebrovascular health, possibly improving postoperative outcome. In addition, isometric handgrip (IHG) training is a promising adjunct lifestyle intervention in order to reduce blood pressure levels and cardiovascular risk. IHG may also be a preconditioning stimulus that lowers tissue injury during surgery that is associated with tissue injury due to periods of (local) ischaemia.
A preoperative physical activity program has been developed in order to promote perioperative health in patients with TAD, involving an existing intervention to promote physical activity levels, reduce SB, and perform IHG training.

Study objective

To compare the effects of a preoperative PA program in addition to usual care

versus usual care only on the change in SB from baseline (T0) to the end of the preoperative (intervention) period (T1) in patients with TAD.

Study design

A randomized controlled trial comparing the preoperative PA program in addition to usual care versus usual care only.

Intervention

In addition to usual care, the intervention group will follow the preoperative PA program, whereas the control group will receive usual care only. The PA intervention involves an existing intervention to reduce SB by wearing a physical activity monitor (Activ8) that provides vibrotactile and web-based feedback, together with additional IHG training (30% MVC, 3x/week). Additionally, patients are weekly coached and supported online or by phone.

Study burden and risks

Since all study procedures and used measurement techniques are non-invasive, the nature and extent of burden and risks associated with the intervention and measurements are negligible.

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 that are:
- visiting the cardiothoracic surgery outpatient clinic prior to probable thoracic aortic surgery;
- aged 18 years or older;
- able to understand and perform study related procedures.

Exclusion criteria

Patients that are:
- unable to provide signed and dated informed consent form;
- wheelchair-bounded or physically unable to stand or walk;
- currently enrolled in another interventional study targeting either sedentary behaviour and/or physical activity.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2021
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO

Date:	25-01-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22457
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75371.091.20
Other	NTR: NL8975
OMON	NL-OMON22457

Study results

Date completed:	08-11-2022

Actual enrolment: 3

Summary results
Trial ended prematurely