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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22457

Source
Nationaal Trial Register

Brief title
Move And Squeeze (MAS) study

Health condition

Thoracic aortic disease

Sponsors and support

Primary sponsor: Radboudumc, Nijmegen, The Netherlands
Source(s) of monetary or material Support: Radboudumc, Nijmegen, The Netherlands

Intervention

Outcome measures

Primary outcome

Perioperative sedentary behaviour, i.e. hours spent sitting/lying during waking hours per day.

Secondary outcome

Perioperative physical activity patterns; perioperative maximal handgrip strength; perioperative resting blood pressure; postoperative occurrence of neurological deficits (e.g. stroke or delirium).

Study description

Background summary

Rationale: Most patients with thoracic aortic disease (TAD), primarily 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 training (IHT) is a promising adjunct lifestyle intervention in order to reduce blood pressure levels and cardiovascular risk. IHT 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 IHT.
Objective: The primary objective of this study is to explore the impact of a preoperative PA program on perioperative SB.
The secondary objectives of this study are to explore the impact of a preoperative PA program on perioperative PA patterns, maximal handgrip strength, resting blood pressure, and the occurrence of postoperative neurological deficits (e.g. stroke or delirium).
Study design: A randomized controlled trial comparing the preoperative PA program in addition to usual care versus usual care only.
Study population: Fifty patients that are visiting the preoperative cardiothoracic surgery outpatient clinic prior to probable TAS.
Intervention: The intervention group will follow the preoperative PA program in addition to

usual care. 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 IHT (30% of maximum voluntary contraction, 3x/week). Additionally, patients are weekly coached and supported online or by phone.
Main study parameters/endpoints: Primary outcome is sedentary behaviour, i.e. hours per day spent sitting or lying during waking hours.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

It is hypothesized that the intervention group (usual care + preoperative physical activity program) reduces sedentary behaviour both pre- and postoperatively compared to the control group (usual care only).

Study design

T0: baseline measurements, approximately 6-12 weeks before surgery;
T1: preoperative measurements, approximately 1-10 days before surgery;
T2: intraoperative measurements;
T3: postoperative measurements, approximately 1-3 days after surgery;
T4: postoperative measurements, approximately 6-12 weeks after surgery.

Intervention

Patients from the intervention group will start the preoperative physical activity (PA) program as soon as possible after all baseline measurements are completed (T0). The intervention will be terminated once the patient is hospitalized 1 day before surgery (T1). As the time between inclusion (T0) and preoperative hospitalization (T1) is dependent on the patients' urgency and present waiting list for thoracic aortic surgery (TAS), the duration of the intervention period will vary between patients. However, it is expected that the PA program can be followed for at least 4 weeks.
During the preoperative PA program, patients are asked to wear the Activ8 (2M Engineering, Valkenswaard, The Netherlands) PA monitor in their pocket, comprising a tri-axial accelerometer. The Activ8 is able to detect sedentary behaviour (SB) and PA, and provides vibrotactile feedback once an uninterrupted sedentary period of 30 minutes is detected. This reminds the patients to replace SB by low-intensity PA (e.g. standing or walking). In a web-based environment, patients are able to review their PA patterns (Figure 3). The Activ8 was previously successfully used for SB reductions in cardiovascular risk patients [16].
In addition to the Activ8, patients will be provided with a hand dynamometer to perform three isometric hand grip training (IHT) sessions per week at home during the intervention period. For each IHT session, patients will be instructed to squeeze and sustain the hand dynamometer 4 x 2 minutes at 30% of maximum voluntary contraction (MVC), alternating hands, with 1 minute rest between bouts. MVC will be determined based on the maximal

handgrip measurement during baseline measurements.
A weekly online meeting or phone call will be organized with the patient in order to coach and support the patient with regard to the PA program, and to reflect on how the intervention is going. The intervention will not affect usual care.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Scheduled for a preoperative visit at 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

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• 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)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	56
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-10-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50977
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8975
CCMO	NL75371.091.20
OMON	NL-OMON50977

Study results