

Exercise for people with an enlargement of the body's main artery

Submission date 06/08/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/09/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/10/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

An enlargement of the main body's artery, the aorta, is an aneurysm of the abdominal aorta (AAA). This is a potentially life-threatening condition. Growth control and preventive surgery are important. It is proven safe to train patients with an AAA. This study is designed to evaluate if training of patients awaiting their surgery are able to improve preoperative aerobic fitness. This fitness is indicated by an increase of VO₂max >1.5 ml/kg/min within 6 weeks. Some patients will benefit more from these training sessions than other patients.

Who can participate?

All patients with an indication for AAA surgery (endovascular and open surgery).

What does the study involve?

Patients will be asked to fill out a questionnaire with a research nurse and visit a cardiologist and a specialist in sports medicine preceding their training. During their six weeks waiting for surgery, patients will be asked to train. Such training sessions will be performed at home, four times a week, and at the physical therapist, once a week. This will be tiresome but rewarding; we expect to accomplish an increase in condition. The elderly seem capable of performing home monitoring. Apart from the extra consultations and the training the patient will not undergo extra laboratory tests other than necessary for regular AAA surgery.

What are the possible benefits and risks of participating?

The benefits are improvement of your condition and less postoperative complications. The improvement of the condition may be beneficial for the rest of your life and will be supported by a specialist in sports medicine and a physical therapist. The reduced complications have been proven for large operations and small operations do not seem to benefit much from training. Risks are small. Earlier, people with an enlargement of the body's main artery thought that exercise was prohibited, but research has proved that exercise does not increase the chance of rupture. We wish to monitor at home, and training is prohibited outside office hours. This enables the research team to educate patients on health-related issues and virtual hospital contact, earlier described as a Surgery School.

Where is the study run from?

Two hospitals in the Northern part of The Netherlands, in cooperation with specialists in sports medicine and physical therapists practises. It is expected to run for a year. Other centers may participate in the Northern part of The Netherlands.

When is the study starting and how long is it expected to run for?

August 2023 to January 2026

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Bastian Vierhout, bas.vierhout@wza.nl

Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Physical therapy for patients with an indication for abdominal aortic aneurysm (AAA) repair; a pilot, correlation study

Acronym

AAiMo

Study objectives

Training of patients awaiting their surgery for an AAA improves preoperative aerobic fitness, indicated by an increase of VO₂max >1.5 ml/kg/min within 6 weeks. Some patients will benefit more from these training sessions than other patients.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 03/09/2024, Medical Research Ethics Committee of the University Medical Center of Groningen (Hanzeplein 1, Groningen, 9700RB, Netherlands; +31 (0)50 361 42 04; metc@umcg.nl), ref: 2023/538

Study design

Interventional non randomized

Primary study design

Interventional

Study type(s)

Prevention, Quality of life

Health condition(s) or problem(s) studied

Patients with an indication for elective abdominal aorta aneurysm (AAA) surgery (endovascular and open surgery).

Interventions

Patients included in these studies must fill out a questionnaire, with the assistance of a research nurse, and perform a cardiopulmonary evaluation. Depending on the outcome and training capability, subjects will start training with home monitoring (pulse oximeter) under the supervision of a physical therapist. Before and after 6 weeks of training, subjects are evaluated by a specialist in sports medicine, to evaluate change of aerobic fitness. In addition, they will be asked to train at their own facility with home monitoring under supervision of a physical therapist.

Intervention Type

Behavioural

Primary outcome(s)

Change in VO₂ at the ventilatory anaerobic threshold (VAT) and oxygen uptake at peak exercise (VO₂peak) after the 6-week prehabilitation program. The VAT will be measured at inclusion (3-9 weeks in advance of the operation) in a cardiopulmonary exercise test (CPET), and again after 3-9 weeks of training. This CPET will report the VAT in ml/kg/min. The difference between the first measurement and the second measurement will be the primary outcome. The oxygen uptake at peak exercise (VO₂peak) will be compared as well.

Key secondary outcome(s)

1. Program feasibility (recruitment rate, adherence, completion rate, drop-out rate, attrition rate, and adverse events) using patient records at the end of the study
2. The (preliminary) effect of the program on other cardiopulmonary exercise testing (CPET) values at inclusion (3-9 weeks in advance of the operation) and again after 3-9 weeks of training
3. The effect of the program with the Luscii-app using a questionnaire at the first postoperative, outpatient control

Completion date

01/01/2026

Eligibility

Key inclusion criteria

All patients with an indication for elective AAA surgery (endovascular and open surgery).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

130

Key exclusion criteria

1. Patients with an acute indication for surgery (symptomatic or ruptured AAAs)
2. Patients with an indication for priority surgery: saccular aspect
3. Patients with tissue disorders (e.g. Marfan or other).

Date of first enrolment

01/11/2024

Date of final enrolment

30/12/2024

Locations

Countries of recruitment

Netherlands

Study participating centre

Wilhelmina Ziekenhuis Assen

Europaweg-Zuid 1

Assen

Netherlands

9401RK

Study participating centre

Treant Ziekenhuis

Boermarkeweg 60

Emmen

Netherlands

7824AA

Sponsor information

Organisation

University Medical Center Groningen

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Bastian Vierhout, bas.vierhout@wza.nl

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4.0	21/07/2024	15/10/2024	No	No