ISRCTN10008907 https://doi.org/10.1186/ISRCTN10008907

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

Submission date 06/08/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/09/2023	**Overall study status** Ongoing	
Last Edited 15/10/2024	**Condition category** Circulatory System	

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Fitness/sport facility, Home, Internet/virtual

Study type(s)
Prevention, Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/08/2023

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
100

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

Sponsor details
Hanzeplein 1
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Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/EN

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We will write a manuscript about the results of this study, which we will submit to a peer-reviewed scientific medical journal. After publication we will make the dataset publicly available.

Intention to publish date
01/01/2026

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