Tonometry(1) and duplex ultrasound(2) to predict cardiovascular events in to be treated patients with an abdominal aortic aneurysm

Published: 11-02-2020
Last updated: 09-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON55391

Source
ToetsingOnline

Brief title
One-Two-Treat Trial

Condition

- Cardiac disorders, signs and symptoms NEC
- Aneurysms and artery dissections

Synonym
Enlargement of the large blood vessel (aorta)/aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Eigen onderzoeksfonds

Intervention

Keyword: Abdominal Aortic Aneurysm, Aneurysm repair, Arterial stiffness, Cardiovascular events

Outcome measures

Primary outcome

The main study endpoint is the incidence of MACE during two year follow-up

(Major adverse cardiovascular events (MACE); including myocardial infarction,

cerebral infarction, heart failure, rupture, and peripheral vascular disease).

Secondary outcome

The following secondary endpoints will be evaluated during the 2-year follow-up:

- SMART risk score

- CAR-test results;

o Percentage of vasodilatation/vasoconstriction to the CAR-test at the common

carotid artery at baseline.

o Magnitude and timing of the blood flow and perfusion response

o Blood pressure and heart rate responses

o Changes after treatment

- SphygmoCor parameters;

o Peripheral pressure measurements (PWA)

o Central and abdominal pressure parameters (derived using a transfer

function) (PWA)

o Cardiac output parameters (SEVR, ED) (PWA)

o PWV

o Changes after treatment

- Score EQ-5D questionnaire

- Score IPQ-K questionnaire

Study description

Background summary

Abdominal aortic aneurysm (AAA) is a common vascular disease and associated with risk of rupture, but also with a high cardiovascular (CV) event rate. A key difficulty in AAA is predicting these life-threatening complications, which are strongly linked to vascular health. In 2013, the SMART risk score is developed to calculate the risk of the patients for recurrent vascular events based on clinical characteristics. Recently, a novel, easy to perform, non-invasive test of endothelial function (the carotid artery reactivity (CAR) test), reflecting target organ damage, has been introduced. The CAR is a simple, quick (5-min), non-invasive test that uses ultrasound to examine the carotid artery in response to sympathetic stimulation by placing one hand in cold water. This test shows strong agreement with both coronary and aortic responses to sympathetic stimulation and predicted cardiovascular events in patients with peripheral arterial disease.

Study objective

The aim of this prospective 2-year follow-up study is to investigate the predictive capacity of the CAR-test for development of cardiovascular events after elective AAA repair in comparison to the SMART risk score. Secondary objectives are to investigate the predictive capacity of the post-operative CAR-test for development of CV-events and to evaluate QoL scores to provide insight if these scores can support clinical decision making.

Study design

Prospective and observational study.

Study burden and risks

In this prospective, observational, explorative study all surgical and medical procedures will performed per standard of care at each participating institutes. The study protocol will collect routine data and will not require

additional patient visits, since the extra measurements (CAR-test and non-invasive arterial stiffness measurements, which takes approximately 30 minutes and is non-invasive) will be performed additional to the clinical visits before and after repair. With these extra measurements, we gain more knowledge about related cardiovascular events to an AAA. When confirming our hypotheses, we expect we can introduce novel, non-invasive, simple technology to support clinical decision-making pertaining to when and whether to treat the aneurysm, but also alter (drug) treatment to reduce risk of cardiovascular events per patient. The used techniques have no risk for the participants. Whilst the CAR-test may cause mild discomfort, which is quickly alleviated after the 3 minute time frame and does not result in any lasting effect. The arterial stiffness measurements cause no discomfort.

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

1. Male or female at least 18 years old;
2. Informed consent form understood and signed and patient agrees to follow-up visits;
3. Has an infrarenal or juxtarenal abdominal aortic aneurysm (AAA), scheduled for elective repair (i.e open repair, EVAR, FEVAR and CHEVAR) according to standard practice

Exclusion criteria

1. Life expectancy < 2 years;
2. Psychiatric or other condition that may interfere with the study;
3. Participating in another clinical study, interfering on outcomes;
4. Increased risk for coronary spasms (score Rose-questionnaire >=2);
5. Presence of Raynaud*s phenomenon, Marfan syndrome, chronic pain syndrome at upper extremity(s), presence of an AV fistula or shunt, open wounds to the upper extremity(s), and/or scleroderma associated with placing the hand in ice water;
6. Recent (<3 months) presence of angina pectoris, myocardial infarction, cerebral infarction, and/or heart failure, or PAD treatment.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-06-2020
Enrollment:	194
Type:	Actual

Ethics review

Approved WMO Date:	11-02-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-09-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-12-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-05-2021
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL69359.091.19