Tonometry (1) and duplex ultrasound (2) to predict Abdominal Aorta Aneurysm (3) progression and cardiovascular events in aneurysm patients

Published: 16-05-2019
Last updated: 09-04-2024

The aim of this prospective 2-year follow-up study is to investigate the predictive capacity of the CAR-test in comparison to the SMART risk score for progression of the abdominal aorta aneurysm and development of cardiovascular events in patients...

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

Summary

ID

NL-OMON48372

Source
ToetsingOnline

Brief title
1-2-3 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, Arterial stiffness, Cardiovascular events, Ultrasound

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, and peripheral vascular disease).

Secondary outcome

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

- SMART risk score;

- 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

-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

-AAA progression (in mm/year);

-AAA repair;

-AAA Rupture;

-Any other (S)AE ;

-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, highlighting the need to explore the potential of novel techniques. Both progression of AAA and CV events 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 recently 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 in comparison to the SMART risk score for progression of the abdominal aorta aneurysm and development of cardiovascular events in patients with an abdominal aorta aneurysm who have not yet reached the treatment threshold. This could aid clinical decision making in the need for (surgical) intervention, but also alter (drug) treatment to reduce risk of cardiovascular events.

Study design

Prospective, observational, explorative study.

Study burden and risks

In this prospective, observational, explorative study all patients will be under surveillance 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 20 minutes and is non-invasive) will be performed additional to the clinical visits. With these extra measurements, we gain more knowledge about novel strategies to predict AAA progression and related cardiovascular events. When confirming our hypotheses, we expect we can introduce novel, non-invasive, simple technology to improve decision-making pertaining to when and whether to treat the aneurysm in AAA-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

Public
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815AD
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815AD
NL

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 abdominal aortic aneurysm (AAA), who is still under surveillance;

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 spams (score Rose-questionnaire *2);
5. Presence of Raynaud*s phenomenon, 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:	Recruitment stopped
Start date (anticipated):	25-07-2019
Enrollment:	167
Type:	Actual

Ethics review

Approved WMO Date:	16-05-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-01-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-09-2020
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	NL68953.091.19

Study results

Date completed:	04-05-2023
Actual enrolment:	167