Relation betwEen abdominal aorta and carotid artery responses to SymPathetic stimulatiON uSing duplEx ultrasound

Published: 24-07-2019
Last updated: 10-04-2024

The aim of this explorative study is to investigate the correlation between the magnitude of the abdominal aorta and the carotid artery diameter and blood flow responses during the sympathetic stimulation (using the cold pressor test) between...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Aneurysms and artery dissections
Study type	Observational non invasive

Summary

ID

NL-OMON48326

Source
ToetsingOnline

Brief title
RESPONSE study

Condition

- Aneurysms and artery dissections

Synonym
abdominal aortic aneurysm, enlargement of the abdominal aorta

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Abdominal Aortic Aneurysm, Carotid artery, Cold pressor test, Ultrasound

Outcome measures

Primary outcome

The main study endpoint is the results of the CPT of the abdominal aorta and

the carotid artery for each participant; this can be either a vasodilation or

vasoconstriction in response to the sympathetic stimulus.

Secondary outcome

Secondary parameters include:

- Other CPT results of the abdominal aorta and the carotid artery

o Magnitude and timing of the blood flow and perfusion response

o Blood pressure and heart rate response

- Age

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. Recent studies suggest that the endothelial function of the abdominal aorta might have a correlation with the disease development. A novel, easy to perform, non-invasive test can assess central artery endothelial function (i.e. the carotid artery reactivity (CAR)). The CAR test is based on the cold pressure test (CPT), which induces sympathetic stimulation by placing one hand in cold water. Using duplex ultrasound, central artery blood flow and diameter responses can be examined.

Previous work has demonstrated that the CPT is associated with an increase in abdominal aortic diameter, whilst others found that the carotid and coronary artery diameter also shows dilation. Interestingly, a previous study found a

strong correlation between carotid and coronary artery diameter responses to the CPT, whilst these artery responses show independent prognostic value for future cardiovascular events in patients with peripheral arterial disease. Possibly, similarity may be present in central artery reactivity to the CPT. To date, no study examined whether carotid and aorta responses are in agreement during the CPT. Given the potential importance of central artery vasoreactivity for AAA, the CAR-test may have potential in this group, especially given the relative simplicity of measuring the carotid artery.

Study objective

The aim of this explorative study is to investigate the correlation between the magnitude of the abdominal aorta and the carotid artery diameter and blood flow responses during the sympathetic stimulation (using the cold pressor test) between healthy young, healthy older and individuals with AAA.

Study design

Explorative, observational study.

Study burden and risks

The test will take approximately 20 minutes, is non-invasive and will provide more knowledge about the correlation between the vasoreactivity of the carotid artery and the abdominal aorta. Upon confirming a correlation, the CAR-test may be further explored as a novel, non-invasive, simple technology to predict AAA-progression and/or improve decision-making pertaining to when and whether to treat the aneurysm in AAA patients. The used technique have no risk for the participants. Whilst the CAR-test may cause mild discomfort, which is quickly alleviated after the 3 minutes frame and does not result in any lasting effect.

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

- Young healthy group: Male or female between the age of 18 and 40 years old;
- Older healthy group: Male or female, which are age-/sex-matched with the AAA patients group;
- AAA patients group: Male or female with an abdominal aortic aneurysm who is still under surveillance, with a diameter between 3.0 and 5.0 cm and at least 18 years old. These patients may participate in the 1-2-3 Trial, which is a similar approved investigation by CMO region Arnhem-Nijmegen with registration number 2019-5216.
- Informed consent form understood and signed;

Exclusion criteria

- Psychiatric or other conditions that may interfere with the study;
- Participating in another clinical study, interfering on outcomes;
- With regard to the necessary quality of the ultrasound images, BMI * 30 kg/m2;
- Increased risk for coronary spasms (score Rose-questionnaire * 2);
- 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;
- Recent (< 3 months) presence of angina pectoris, myocardial infarction, cerebral infarction, and/or heart failure, or PAD treatment.
- Healthy groups:

o Systolic blood pressure >140 mmHg and/or diastolic blood pressure >90 mmHg
o Cardiovascular history
o Antihypertensive medication

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):	01-10-2019
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	24-07-2019
Application type:	First submission
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	NL70352.091.19

Study results

Date completed:	05-10-2020
Actual enrolment:	60