The clinical prognostic value of the carotid artery reactivity test in patients with peripheral artery disease

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To examine the 1- and 3-year prognostic value of the CAR-test in patients with peripheral artery disease regarding the occurrence of vascular complications and the progression of PAD

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40126

Source
ToetsingOnline

Brief title
Prognostic value CAR-test

Condition

- Other condition

Synonym
peripheral artery disease

Health condition

vasculaire aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: carotid artery, endothelial function, peripheral artery disease, prognostic value

Outcome measures

Primary outcome

The occurrence of vascular complications and the progression of peripheral

artery disease

Secondary outcome

n.a.

Study description

Background summary

Peripheral artery disease (PAD) is a common disease and is associated with serious health problems. A number of clinical tests have been developed to assess prognosis and progression of PAD, such as the ankle-brachial-index (ABI). Previous studies have demonstrated that measures of cardiovascular function significantly contribute to the predictive capacity of the ABI. However, these previous studies used techniques that are expensive, invasive and/or technically challenging.

The carotid artery reactivity(CAR)-test relates to the assessment of the carotid artery diameter changes in response to a stimulus of the sympathetic nervous system, induced by a cold pressor test (placing the hand in icy water). In analogy with coronary vessels (but not with peripheral conduit arteries), the carotid artery responds with a dilation (of ~10%). However, the presence of cardiovascular risk/disease leads to an attenuation of the dilator response, or could even lead to a small constriction of the carotid artery (of ~5%). This simple, non-invasive and easy applicable test may contribute to the risk stratification or prediction of complications of PAD patients. To date, no previous study examined the potential prognostic value of the CAR-test in PAD

patients.

Study objective

To examine the 1- and 3-year prognostic value of the CAR-test in patients with peripheral artery disease regarding the occurrence of vascular complications and the progression of PAD

Study design

Observational, prospective cohort study

Study burden and risks

Performance of the CAR-test takes approximately 5 minutes and will be performed immediately after the (planned) tests in the vascular laboratory (which takes 30 minutes). The CAR-test is non-invasive and associated with a minimal burden. Therefore, the CAR-test is associated with a minimal burden for the patients, whilst the results of this study may have important and novel clinical value, potentially leading to a significant improvement in the clinical care of this group of patients.

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

- Patients with peripheral artery disease (Fontaine 2b-3-4)
- >= 18 years
- Mentally capable to sign an informed consent

Exclusion criteria

- Presence of Raynaud, chronic pain syndrome in upper limbs, shunt, open wound in upper limb and/or sclerodermia
- Recent (<6 months) intervention for coronary, central or peripheral artery disease
- Recent (<3 months) presence of unstable angina pectoris, myocardial infarction, cerebral infarction, and/or heartfailure.

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):	30-06-2014

Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-05-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-06-2014
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	NL46109.091.13