Improvement of prognosis in patients with peripheral artery disease using a novel test.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23257

Source NTR

Brief title Prognosis CAR-PAD

Health condition

peripheral artery disease peripheral artery occlusive disease

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre **Source(s) of monetary or material Support:** Radboud University Nijmegen Medical Centre

Intervention

Outcome measures

Primary outcome

-Occurrence of vascular complications

1 - Improvement of prognosis in patients with peripheral artery disease using a nove ... 4-05-2025

-Clinical progression of disease state (walking distance, Fontaine classification, amputation)

Secondary outcome

-Physiological progression of disease state (ankle-brachial index)

Study description

Background summary

Background of the study:

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 $\sim 10\%$). 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 \sim 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

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.

Objective of the study:

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 population:

200 patients with peripheral artery disease

Primary study parameters/outcome of the study:

The occurrence of vascular complications and the progression of peripheral artery disease

Study objective

The carotid artery reactivity-test will have independent prognostic value compared to the current, standard prognostic tests (i.e. ankle-brachial-index, walking distance) for patients with peripheral artery disease

Study design

0, 1 and 3 years

Intervention

performance of the carotid artery reactivity test at the entry of the study (in addition to the standard tests)

Contacts

Public

Phililps van Leijdenlaan 15 Dick H.J. Thijssen Nijmegen 6525 EX The Netherlands +31 (0)24 3614222 **Scientific** Phililps van Leijdenlaan 15

Dick H.J. Thijssen Nijmegen 6525 EX The Netherlands

3 - Improvement of prognosis in patients with peripheral artery disease using a nove ... 4-05-2025

Eligibility criteria

Inclusion criteria

- Patients with peripheral artery disease (Fontaine 2b-3-4)
- Ankle-Brachial index of <0.90
- ≥ 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
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2013
Enrollment:	200
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	15-08-2013
Application type:	First submission

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
NTR-new	NL3951
NTR-old	NTR4117
Other	NL46109.091.13 : Dick Thijssen
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

5 - Improvement of prognosis in patients with peripheral artery disease using a nove ... 4-05-2025

N/A