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

Gepubliceerd: 15-08-2013 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23257

Bron
NTR

Verkorte titel
Prognosis CAR-PAD

Aandoening

peripheral artery disease
peripheral artery occlusive disease

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Overige ondersteuning: Radboud University Nijmegen Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 ~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.

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

Doel van het onderzoek

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

Onderzoeksopzet

0, 1 and 3 years

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients with peripheral artery disease (Fontaine 2b-3-4)

- Ankle-Brachial index of <0.90

- ≥ 18 years

- Mentally capable to sign an informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm

Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2013
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3951
NTR-old	NTR4117
Ander register	NL46109.091.13 : Dick Thijssen
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A