Reproducibility of the carotid artery vasoreactivity test

Published: 15-12-2014
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To examine the hour-to-hour and day-to-day reproducibility of the CAV-test in young and older humans

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON41758

Source
ToetsingOnline

Brief title
Reproducibility CAV

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cardiovascular disease

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: cardiovascular disease, echo-Doppler, endothelial function

Outcome measures

Primary outcome

The relative change in diameter during the CAV

Secondary outcome

N.A.

Study description

Background summary

Cardiovascular disease remains the world's leading cause of mortality and morbidity. In the development of cardiovascular disease, the presence of endothelial dysfunction plays a crucial step. It has been demonstrated that the presence of endothelial dysfunction precedes the development of artherosclerosis. Identification of the presence of endothelial dysfunction, therefore, has important clinical implications.

A few years ago, the carotid artery vasoreactivity (CAV) test was introduced. The CAV demonstrates distinct responses between healthy subjects and those with cardiovascular risk. During the CAV-test, the carotid artery diameter response is measured in response to a strong activation of the sympathetic nervous system by putting a hand in a bucket of ice water. In analogy with coronary arteries (but not peripheral arteries), this test causes a strong dilation of the carotid artery (of ~10%) in healthy subjects. Interestingly, subjects with cardiovascular risk factors or those with cardiovascular disease demonstrate a small or even absent dilation, or even a constriction. The assumption is that this simple, non-invasive test provides information about the endothelial function and may possess prognostic value. However, currently little is known about the reproducibility of this test in young or older humans. This information is important to appropriately design future studies that adopt the CAV.

Study objective

To examine the hour-to-hour and day-to-day reproducibility of the CAV-test in young and older humans

Study design

Observational cohort study

Study burden and risks

Assessment of the CAV takes 5 minutes, which is preceded by a 20 minute resting period. The CAV-test is non-invasive and associated with minimal burden. Therefore, our experiments only places a minimal burden on the subjects, in time as well as physically.

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

-Younger subjec ts (18-30 years)

-Older subjects (>50 years)
-Mentally capable of providing informed consent

Exclusion criteria

- Increased risk coronary spasms
-Presence of Raynaud's phenomenon, chronic pain syndrom in extremities, presence of AV-fistel or shunt, open wounds and/or sklerodermia
-Recent (<3 months) presence of angina pectoris, myocardial infarction, stroke or heart failure

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):	22-01-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2014
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	NL51166.091.14

Study results

Date completed: 24-09-2015

Actual enrolment: 50

Summary results
Trial is onging in other countries