Impact of cardiovascular risk factors on arterial wall thickness

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37428

Source
ToetsingOnline

Brief title
Cardiovascular riskfactors and wall thickness

Condition

- Other condition

Synonym
atherosclerosis

Health condition

hypertensie

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: atherosclerosis, cardiovascular risk, wall thickness

Outcome measures

Primary outcome

1) Wall thickness

2) Flow-mediated dilation

Secondary outcome

not applicable

Study description

Background summary

Atherosclerosis is an important proces that contributes to the development of cardiovascular disease. Atherosclerosis is characterised by thickening of ther arterial wall. Several studies found that the carotid artery wall thickness is a good measure for the process of atherosclerosis and has a strong predictive capcity for future cardiovascular events. These studies primarily focused on the carotid artery, but relatively little is known about the process of wall thickening in other arteries in the upper and lower limbs. In addition, little is known whether the impact of hypertension on carotid artery wall thickening is similar to that observed in arteries of the lower and upper limbs.

In the 1950s, Prof. Folkow provided evidence that a thicker wall is related to a larger responsiveness of the same artery. Recently, we could confirm this hypothesis for conduit arteies in healthy young men as a larger dilator responsiveness was observed in arteries with thicker walls. Whether a similar relation is also present in subjects with cardiovascular risk factors (which typically lead to thickening of the arterial wall) is currently unknown.

Study objective

Objective 1: to examine the relation in wall thickness and diameter across arteries that are prone (i.e. carotid, femoral, superficial femoral and popliteal) and resistant (i.e. brachial and radial) against atherosclerosis in healthy volunteers and those with hypertension.
Objective 2: to examine the relation between wall thickness and dilator function in healthy volunteers and those with hypertension.

Study design

observational, cross-sectional pilot study

Intervention

n/a

Study burden and risks

Subjects will visits our laboratory twice; once for a screening (0.5 h) and once for the test (2 h). During the test, we will measure diameter and wall thickness of the carotid, brachial, radial, femoral, superficial femoral and popliteal artery. In addition, we will examine the endothelium-dependent and independent dilation of the brachial and superficial femoral artery. This will be performed with non-invasive tests with a minimal burden for the subjects.

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

Subjects with hypertension (diastolic >90 and/or systolic >140 and/or use of medication against hypertension) and their age- and sex-matched controls.;Subjects with hypertension have a blood pressure (after 5 min seated rest, measured twice) of >=140 systolic or >=90 diastolic blood pressure or the use of prescribed anti-hypertension medication.

Exclusion criteria

For all subjects
- Diagnosis of cardiovascular disease
- Diabetes Mellitus type I or II
- smoking
- women on hormone replacement therapy
- Family history of acute cardiac death (< 50 years of brother/sister or father/mother).
- Hypercholesterolemia (>=6.5 mmol/L or use of statins).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2012
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	NL38908.091.11