Measurement of local arterial stiffness in the carotid artery in subjects at low and high cardiovascular risk and in patients with recent ischaemic cerebrovascular events.

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

Summary

ID

NL-OMON43542

Source
ToetsingOnline

Brief title
Local PWV assessment with MRI

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arterial stiffness, cardiovascular risk

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Arterial stiffness, Atherosclerosis, Atherosclerotic plaques, Cardiovascular risk

Outcome measures

Primary outcome

The principal parameter is the difference in local PWV as measured by MRI at three different points in the carotid artery in (symptomatic and asymptomatic) patients with carotid plaque formation and in healthy controls.

Secondary outcome

As secondary parameters we will consider the difference in vessel wall dimensions, wall shear stress and PWV between healthy subjects and (symptomatic and asymptomatic) cardiovascular patients.

Study description

Background summary

Atherosclerosis is the main cause of cardiovascular disease. It is a progressive disease, characterised by the formation of plaques in the vessel wall. In the past decades, the management of cardiovascular (CV) disease has been revolutionised by the advent of preventive strategies. Despite a tremendous improvement with this risk stratification, a number of patients still remain unidentified until a primary event occurs. Therefore, additional tools to identify high-risk patients are under evaluation. Global pulse wave velocity (PWV), an index of arterial stiffness, is considered to be an early marker of atherosclerosis but can give only little information regarding local changes in vessels prone to atherosclerotic disease. Therefore, local PWV assessment through MRI could be of great interest, especially considering than MRI enable us to assess both functional and morphologic characteristics

Study objective

The main goal of this study is to assess the difference in local pulse wave velocity measured at three different points in the left and right carotid artery in healthy subjects and in patients with symptomatic and asymptomatic carotid plaques. As secondary objectives, we aim to assess the difference in vessel wall dimensions, wall shear stress, global pulse wave velocity between healthy subjects and cardiovascular patients and to investigate the correlation between pulse wave velocity, wall shear stress and atherosclerotic plaque characteristics.

Study design

Cross-sectional study

Study burden and risks

The results of this study contribute to the quality of novel techniques in atherosclerotic imaging, thereby contributing to risk stratification in individual patients and testing of new anti-atherosclerotic treatment. Individual subjects will gain no direct benefit from this study. The risk of participating in this study is low. MRI is a safe imaging technique without radiation exposure. Gadovist is routinely used as a contrast agent in magnetic resonance imaging.

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

Group 1 : subjects aged >18 years with asymptomatic carotid plaques as assessed by either carotid ultrasound/CT or previous MRI
Group 2 : subjects aged >18 years with symptomatic carotid artery disease as evidenced by a recent TIA or ischaemic stroke in the supply area of the carotid artery in the preceding 8 months not scheduled for intervention
Group 3 : healthy volunteers aged >18 years with no history of cardiovascular disease nor presence of cardiovascular risk factors

Exclusion criteria

Exclusion criteria for all subjects
• Known systemic disorders such as hepatic, renal, haematological and malignant diseases or any clinically significant medical condition that could interfere with the conduct of the study in the opinion of the investigator
• Standard contra-indications to MRI based on physicians experience and current practices
• Inability or unwillingness to comply with the protocol requirements, or deemed by investigator to be unfit for the study;Exclusion criteria for group 1
• Changes in dose or frequency of doses of lipid-lowering drugs, antihypertensive drugs or antidiabetic drugs in the last 6 weeks prior to baseline measurements
• Cerebrovascular event in the 8 months prior to enrolment;Exclusion criteria for group 2
• Changes in dose or frequency of doses of lipid-lowering drugs, antihypertensive drugs or antidiabetic drugs in the last 6 weeks prior to baseline measurements;Exclusion criteria for group 3
• History of cardiovascular disease
• Presence of risk factors for cardiovascular disease
• Use of any cardiovascular medication, including but not limited to lipid-lowering therapy, antihypertensive drugs, anti-diabetic drugs, platelet aggregation inhibitors and anticoagulants

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-02-2016
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	14-01-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL55762.018.15