Study to investigate the sensitivity and specificity of 3.0 Tesla MRI, MRS and ultrasound imaging for carotid artery plaque dimension and composition assessment.

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PrimaryTo investigate sensitivity and specificity of 3.0 Tesla MRI and MRS for dimension and composition assessment of carotid artery plaques, in particularly those plaques with lipid rich necrotic cores (LRNC), with the aim to develop these...

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

Summary

ID

NL-OMON36476

Source
ToetsingOnline

Brief title
TIP-H

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis, n/a

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Atherosclerosis, Carotid MRI, Histology, Validation

Outcome measures

Primary outcome

Imaging

1. Total plaque volume, plaque calcification volume, plaque haemorrhage volume, lipid rich necrotic core volume, fibrous cap thickness, as assessed by 3.0 Tesla MRI.

2. The ratio of the integrated lipid peak versus the unsuppressed water peak (expressed as a percentage), as assessed by MRS.

3. Carotid plaque presence and location, maximum plaque thickness and plaque composition, as assessed by B-mode ultrasound imaging.

4. Carotid intima-media thickness, arterial stiffness, blood flow velocity measured by ultrasound imaging.

Histology

5. Plaque size, morphology and phenotype (presence of collagen, smooth muscle cells, calcifications, macrophages, thrombus and fat), as assessed by histology analysis.

Secondary outcome

no secundary study parameters

Study description

Background summary

Atherosclerosis is a protracted and in fact lifelong progressive disease. Over time, lipids accumulate in the artery wall forming fatty streaks, which eventually can develop into atherosclerotic plaques (1). The later stages of the process, from quiescent atherosclerotic plaque to an active plaque, have a high risk of triggering acute vascular events, such as myocardial infarction and stroke (1).
Much effort has been put in the development of novel drugs aimed to prevent cardiovascular disease. Low Density Lipoprotein cholesterol (LDL-C) lowering drugs, in particularly statins, play a pivotal role. The hypothesis that serum lipid lowering results in decrease of lipid accumulation in the arterial wall and thus atherogenesis, has formed the basis for successful drug developing strategies (1;2).

To draw valid conclusions on determinants of disease and effectiveness of lipid modifying therapeutic intervention, imaging of atherosclerosis can be used as a validated tool to assess efficacy of novel compounds (3;4).
Although imaging arterial wall dimensions by B-mode ultrasound and intra-vascular ultrasound have proven their value, longitudinal data of the effects of cardiovascular drugs on arterial wall and plaque composition, in particular of vulnerable plaques with lipid rich necrotic cores (LRNC), are scarce.

Magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS) are non-invasive imaging modalities that can potentially image plaque composition in-vivo in human carotid arteries. MRI image acquisition at various weightings enables visualisation of plaque composition. Calcification, haemorrhage, fibrous cap and lipid rich necrotic cores can readily be distinguished, providing information on plaque vulnerability. MRS gives a spectrum of resonances, affording detection of specific chemical components through their inherent frequency shift relative to water (5). In image guided MRS, an MR image can be utilized to image and localize a plaque. Proton spectra can then be collected from these plaques, such that the specific proton resonances of lipid components in a mobile state, including cholesterol ester (CE), can be identified (6).

Study objective

Primary
To investigate sensitivity and specificity of 3.0 Tesla MRI and MRS for dimension and composition assessment of carotid artery plaques, in particularly those plaques with lipid rich necrotic cores (LRNC), with the aim to develop these techniques to validated tools for clinical investigations and trials.

Secondary
To investigate sensitivity and specificity of carotid B-mode ultrasound imaging as a pre-screening assessment of carotid plaques for MRI and MRS studies.

Study design

This is a non-invasive cross-sectional study, comparing carotid parameters of in-vivo 3.0 Tesla MRI, MRS and B-mode ultrasound with histology specimens collected at endarterectomy.

Study burden and risks

This study is conducted using non-invasive imaging technologies: MRI, MRS and ultrasound imaging. There is no risk associated with participation.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

carotid artery stenosis, > 70 %, scheduled for carotid endarterectomy

Exclusion criteria

Not suitable for MRI (e.g. metal in the body, e.g. as a result of pacemaker or artificial cardiac valve implant), claustrophobia, former surgical procedures in the carotid area

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO
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	NL28938.018.09