Study to investigate possible applications for MRI and ultrasound in the diagnosis of atherosclerosis of the carotid artery.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26704

Source
Nationaal Trial Register

Brief title
TIP-H

Health condition

Patients with a ≥70% carotid artery stenosis on clinical ultrasound duplex examination and are scheduled for endarterectomy

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: research grant MERCK

Intervention

Outcome measures

Primary outcome

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.

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 B-mode 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.

For the comparison of histology and MRI, MRS and ultrasound images the histological images are matched by observing the overall morphology such as lumen size and shape, wall size and shape, plaque configuration, as well as calcifications, landmarks of the plaque and the known distance of each slice from the common carotid bifurcation. Histology slices will be matched with MR images and ultrasound images based on anatomical landmarks.

Secondary outcome

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 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

Magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS) are non-invasive imaging modalities that can image plaque composition in-vivo in human carotid arteries with high sensitivity and specificity with regards to calcification, haemorrhage, fibrous cap and lipid rich necrotic cores.

Study design

N/A

Intervention

N/A

Contacts

Public

Meibergdreef 9, F4-121
Stroes
Amsterdam 1105 AZ
The Netherlands
Scientific
Meibergdreef 9, F4-121
Stroes
Amsterdam 1105 AZ
The Netherlands

Eligibility criteria

Inclusion criteria

1. Patients are to meet the inclusion criteria of the Athero-Express study;

2. These patients are eligible to undergo carotid endarterectomy in either the St. Antonius Hospital, Nieuwegein;

3. Willing and able to undergo non-invasive MRI, MRS and ultrasound examinations in the Academic Hospital Center, Amsterdam;

4. Signed informed consent.

Exclusion criteria

1. Patients not suitable for MRI (e.g. metal in the body, as a result of pacemaker or artificial cardiac valves);

2. Claustrophobia;

3. Surgery performed in the neck area of the carotid measurements.

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2010
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-07-2010
Application type:	First submission

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
NTR-new	NL2308
NTR-old	NTR2414
Other	METC AMC : 09/182
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A