MR Intracranial Vessel wall Imaging in ischemic stroke patients, TIA patients and controls

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We hypothesize that intracranial vessel wall atheromas are an important underlying cause of middle cerebral artery obstruction. To test our hypothesis we will perform high resolution intracranial vessel wall imaging with a 7.0 Tesla MRI scanner in...

Ethical review	Not approved
Status	Will not start
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32985

Source
ToetsingOnline

Brief title
IVI study

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Vessel wall atheroma; artery hardening

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: CTMM

Intervention

Keyword: Atherosclerosis, Intracranial arteriosclerosis, Magnetic Resonance Imaging

Outcome measures

Primary outcome

Our main study parameter is the presence or absence of intracranial atherosclerosis in one (or more) arteries of the anterior cerebral circulation in the aforementioned groups.

Secondary outcome

Secondary study parameters are signal characteristics of the intracranial vessel wall atheroma on multiple MRI-sequences and two different magnetic field strengths, combined with histology as golden standard if applicable. Our (secondary) outcome will be cognitive functioning of the subject, in association with possible microvascular damage.

Study description

Background summary

Atherosclerosis of the intracranial arteries has been shown to be correlated with a high recurrent stroke risk. Especially, patients with a hyperdense vessel sign on CT are known to have a very poor prognosis with a high morbidity and mortality. Microvascular damage (microbleeds, microinfarcts) could also play a role in this context, which is associated with cognitive decline. To the best of our knowledge no previous research has been performed to characterize the intracranial arterial vessel wall, or to investigate a possible correlation between vessel wall abnormalities, microvascular damage and cognitive funtioning.

Study objective

We hypothesize that intracranial vessel wall atheromas are an important underlying cause of middle cerebral artery obstruction. To test our hypothesis

we will perform high resolution intracranial vessel wall imaging with a 7.0 Tesla MRI scanner in stroke patients, TIA patients and controls. As secondary objectives we will characterize the intracranial vessel wall atheroma with correlation to histology, and we will compare intracranial vessel wall imaging with 7.0 Tesla and 3.0 Tesla. We will also investigate microvascular damage and cognitive functioning. With these data we will not only be able to visualise the intracranial arterial vessel wall to obtain information on presence of atherosclerosis, but we could also ultimately provide valuable information regarding possible presence of an instable atheroma. Also, a statement can be made regarding a possible correlation between microvascular damage, cognitive functioning and intracranial atherosclerosis.

Study design

For collection of data, all stroke patients and TIA patients will undergo a first 7.0 Tesla MRI scan within 1 week after initial ischemic symptoms; a second 7.0 Tesla MRI scan will be performed 1 month after initial ischemic symptoms. A subgroup of 20 TIA patients will undergo an MRI scan in a 3.0 Tesla MRI scanner, in addition to the two 7.0 Tesla MRI-scans, for comparison with 7.0 Tesla results. Healthy controls will undergo a 3.0 Tesla and 7.0 Tesla MRI scan. Histology samples will be scanned with 3.0 and 7.0 Tesla MRI. All subjects will also undergo neuropsychological tests.

Study burden and risks

Stroke- and TIA patients will undergo a first 7.0 Tesla MRI scan within 1 week after onset of ischemic symptoms; the second 7.0 Tesla MRI scan will be performed 1 month later. A subgroup of TIA patients will undergo a 3.0 Tesla MRI scan in addition to the 7.0 Tesla MRI-scans, which will be planned if possible in combination with the second MRI scan to prevent frequent visits to the UMCU. This also applies to the controls, who will be scanned with both 3.0 and 7.0 Tesla MRI scanner. During one of the visits neuropsychological tests will also be performed. Subjects will be screened for contraindications for MRI and contrast agent, to reduce possible risks to a minimum.

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

Main inclusion criteria for stroke patients and TIA patients:
• 18 years or older
• Male or female
• Ready for MRI scanning within 1 week after onset of ischemic symptoms;Additional inclusion criteria for stroke patients:
• Ischemic symptoms conform PACI/TACI (Partial/Total Anterior Circulation Infarct)
• CT acute stroke imaging protocol: area of ischemia of the cerebral anterior perfusion territory based either on anatomical CT images or on CT perfusion images;Additional inclusion criteria for TIA patients:
• Transient ischemic symptoms (< 24 hours of duration) conform PACS/TACS (Partial/Total Anterior Circulation Syndrome)
• No area of ischemia visualized on either anatomical CT images or on CT perfusion images

Exclusion criteria

• Stroke patients with either a hyperdense vessel sign on CT or occlusion of an artery of the anterior cerebral circulation on CT angiography, but not both or neither
• Patients with a known cardiac cause of stroke
• Patients with a stroke secondary to surgical / interventional procedures
• Allergic reaction to gadolinium
• Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the

body)

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:	Will not start
Enrollment:	180
Type:	Anticipated

Ethics review

Not approved

Date:	12-05-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL27873.041.09