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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON47383

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,ERC Grant Heart of Stroke

Intervention

Keyword: Atherosclerosis, Intracranial artherosclerosis, 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

Our secondary study parameters are signal characteristics of the intracranial vessel wall atheroma, specifically unstable atheroma, on multiple MRI sequences, and assessment of clinical consequences of intracranial atherosclerosis by evaluation of standard brain imaging.

Furthermore we would like to evaluate the accuracy and utility of the short vessel wall sequence compared to the current more time-consuming vessel wall sequence. We will assess whether this short vessel wall sequence has the potential to replace the longer vessel wall sequence in future.

Study description

Background summary

Atherosclerosis of the intracranial arteries has been shown to be correlated with a high recurrent stroke risk. To the best of our knowledge, no previous research has been performed to characterize the intracranial arterial vessel wall.

Study objective

We hypothesize that intracranial vessel wall atheromas are an important underlying cause of obstruction of (one of the) artery(ies) of the anterior cerebral circulation. To test our hypothesis we will perform high resolution intracranial vessel wall imaging with a 7.0 Tesla and 3.0 Tesla MRI scanner in stroke patients and TIA patients. To obtain a basic understanding of the possible clinical and subclinical consequences of these intracranial vessel wall atheroma, we will also image the whole brain. 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, by describing signal characteristics of these atheroma, and provide a basic understanding of the possible consequences of atherosclerosis of intracranial arteries.

Study design

For collection of data, all stroke patients and TIA patients will undergo a 7.0 Tesla MRI scan within 3 months after initial ischemic symptoms, together with collection of baseline characteristics. A 3.0 Tesla MRI scan will be also performed within 3 months.

Study burden and risks

Patients receive 2 MRI scans, the first one within one month after onset of symptoms, the second one within 3 months after the first scan. Baseline characteristics of all subjects will be collected, and all patients will undergo one session. To reduce possible risks to a minimum, subjects will be screened for contraindications for MRI and contrast agent.

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 3 months after onset of ischemic symptoms;Additional inclusion criteria for stroke patients:
• Ischemic symptoms conform PACI/TACI (Partial/Total Anterior Circulation Infarct);Additional inclusion criteria for TIA patients:
• Transient ischemic symptoms (< 24 hours of duration) conform PACS/TACS/LACS (Partial/Total/Lacunar Anterior Circulation Syndrome)

Exclusion criteria

• Patients with a stroke secondary to surgical / interventional procedures
• Allergic reaction to gadolinium
• Patients with impaired renal function (severe renal insufficiency, GFR < 30ml/min/1,73m2; or nephrogenic systemic fibrosis / nephrogenic fibrosing nephropathy (NSF/NFD))
• Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body)
• Patients who cannot be scanned <3 months.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2009
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	29-09-2009
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	26-03-2010
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-10-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-10-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-08-2018
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22252
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL28606.041.09
Other	NTR2119 (www.trialregister.nl)
OMON	NL-OMON22252