Intracranial vessel wall MR imaging at 3.0 and 7.0 tesla in patients with TIA or ischemic stroke of the posterior circulation

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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-OMON47288

Source
ToetsingOnline

Brief title
PIVI Study

Condition

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

Synonym
atherosclerosis, hardening of the arteries

Research involving
Human

Sponsors and support

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

Intervention

Keyword: intracranial, MRI, stroke, vessel wall

Outcome measures

Primary outcome

The presence or absence of intracranial vessel wall abnormalities in arteries of the intracranial posterior circulation. Presence of atherosclerosis is defined as any irregularity of the arterial vessel wall.

Secondary outcome

- Number of vessel wall abnormalities in the intracranial vessel wall MRI scan at 7.0 tesla as compared to 3.0 tesla.

- Characteristics of intracranial vessel wall atheroma, by discriminating different MRI signal intensities in the vessel wall atheroma.

- The clinical outcome measures (e.g. occurrence of vascular events, level of handicap, current medication) collected during follow-up.

Study description

Background summary

Intracranial atherosclerosis is an important cause of ischemic stroke and transient ischemic attack (TIA). Development of atherosclerotic lesions occurs silently over a longer period of time, until they become symptomatic. Most non-invasive intracranial imaging methods (transcranial Doppler, MRA, CTA) are based on visualizing the lumen of the intracranial vasculature, thereby giving indirect information about the underlying vessel wall abnormalities caused by atherosclerosis. Because of arterial remodelling in which the luminal diameter

remains equal despite the presence of an underlying atheroma, these lumenography techniques may result in underdiagnosis of intracranial atherosclerosis.

At the UMC Utrecht, within the 7.0 tesla group of Prof Luijten, an MRI sequence at 7.0 tesla was developed specifically for imaging of both healthy and abnormal intracranial vessel walls, and is currently being used in an on-going study (IVI Study) including patients with (transient) ischemia in the anterior cerebral circulation. Previous intracranial vessel wall MR imaging studies have mainly focused on the anterior circulation, where ischemia is most common. Ischemic stroke or TIA in the posterior circulation accounts for approximately 20 to 30% of all ischemic events. We hypothesize that arterial vessel wall abnormalities are also common in the posterior circulation, and are an important underlying cause of obstruction of arteries in the intracranial posterior circulation and subsequent ischemic stroke. Ultimately, for wide clinical application of intracranial vessel wall imaging, a translation has to be made to lower field strength MR scanners (3.0 tesla). Therefore, based on the 7.0 tesla intracranial vessel wall MR imaging protocol, we have developed a 3.0 tesla protocol for clinical implementation.

Study objective

The primary objective of the current study is to compare the presence or absence of arterial vessel wall abnormalities in the intracranial posterior circulation in patients with TIA or ischemic stroke with those of healthy controls using 7.0 tesla MRI.

The secondary objective is to assess the sensitivity of 3.0 tesla MRI to detect the vessel wall abnormalities visualised with 7.0 tesla MRI.

Tertiary objectives will be:
(i) characterization of intracranial arterial vessel wall atheroma, specifically unstable atheroma by evaluating the signal characteristics on multiple MRI sequences, including enhancement after contrast administration;
(ii) to compare the presence of intracranial arterial vessel wall abnormalities between patients with posterior and anterior circulation TIA or ischemic stroke, by combining our data with those of the on-going IVI Study;
(iii) to assess the possible correlation between the observed arterial vessel wall abnormalities and the occurrence of vascular events during follow-up.

Study design

This study is a single-center, prospective case-control study. Intracranial vessel wall imaging will be performed with a 3.0 tesla and a 7.0 tesla MRI scanner in patients with TIA or ischemic stroke of the posterior circulation, and age- and sex-matched healthy controls, combined with standard clinical

imaging of the brain on these platforms.

Baseline characteristics of all patients and healthy controls will be collected at inclusion into our study. All participating subjects (ischemic stroke/TIA patients and healthy controls) will undergo one 3.0 tesla and one 7.0 tesla MRI examination. In patients, both MRI examinations will be performed as soon as possible, but at the latest within 3 months, after the onset of ischemic symptoms. A minimum of 12 hours is taken in between both examinations, to make sure the contrast agent has washed out sufficiently. Clinical follow-up of the patients will be performed at 3 months and at 1, 2, and 3 year(s) after study inclusion, consisting of a brief survey conducted by telephone, and by collecting data on recurrent vascular events. The healthy controls will not receive clinical follow-up.

Study burden and risks

The results of this study will further unravel the contribution of intracranial atherosclerosis to posterior circulation ischemia, and its prevalence in patients with ischemic stroke as well as healthy individuals. The translation of 7.0 tesla intracranial vessel wall MR imaging to 3.0 tesla will make wide clinical application possible. There will be no direct benefits for the individual subjects participating in this study. But in the future we feel that the aforementioned MR measurements of intracranial atherosclerosis may be important to guide decisions about preventive treatment in patients with a high risk of (recurrent) stroke.

Risk assessment MRI:
To the best of our knowledge there are no short- or long-term risks involved of having an MRI scan. Participants are not requested to have any precautions or actions prior to or following to the MRI exam.

Risk assessment contrast agent:
The contrast agent Gadobutrol (Gadovist ®) is used. This is the standard contrast agent used in MR imaging examinations in the clinical setting, and as such it is administrated to thousands of patients every year at the UMC Utrecht. Gadovist is registered in the Register of Pharmaceuticals (RVG 25318). A standard amount of 0.1 mL/kg bodyweight will be administered.

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

>= 18 years of age;Additional inclusion criteria for ischemic stroke / TIA patients:
- TIA or ischemic stroke in the posterior circulation territory (= supplied via the vertebral and basilar arteries or their branches)
- Possibility to perform MRI scanning within 3 months after onset of relevant ischemic symptoms

Exclusion criteria

- Allergic reaction to gadolinium or one of the constituents of its solution for administration
- Impossibility to undergo MRI (claustrophobia, implants or metal objects in or around the body)
- Severely impaired renal function (severe renal insufficiency, GFR < 30ml/min/1,73m2; or nephrogenic systemic fibrosis / nephrogenic fibrosing nephropathy (NSF/NFD))
- Pregnancy;Additional exclusion criteria for ischemic stroke / TIA patients:
- A TIA or ischemic stroke secondary to a surgical or interventional procedure
- Previous vertebrobasilar surgery or endovascular therapy

Additional exclusion criteria for healthy volunteers:

- History of cerebral events (e.g. ischemic stroke, TIA, hemorrhage)

Study design

Design

Study type:	Observational 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):	07-11-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	16-07-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	07-12-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-08-2018
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: 20531
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43704.041.13
Other	NTR5688 (www.trialregister.nl)
OMON	NL-OMON20531