High-resolution MR imaging of intracranial arteries and vessel wall, a feasibility study

Published: 23-04-2014
Last updated: 20-04-2024

the main objective of this study is to evaluate the ability and reproducibility of high-resolution 3 Tesla MR imaging to visualise intracranial arteries and intracranial atherosclerotic disease in patients with previous TIA or ischemic stroke.

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

Summary

ID

NL-OMON40929

Source
ToetsingOnline

Brief title
HR-MRI of intracranial arteries and vessel wall

Condition

- Central nervous system vascular disorders

Synonym
intracranial atherosclerotic disease (IAD)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: high-resolution MRI, intracranial arteries, intracranial atherosclerotic disease, vessel wall imaging

Outcome measures

Primary outcome

The intracranial part of the internal carotid artery, the M1 segment of the

middle cerebral artery and the basilar artery will be imaged. The visibility of

both vessel lumen and vessel wall will be assessed based on the following

parameters:

- Image quality, resolution, signal to noise ratio

- Vascular lumen area on MRI (compared with CTA where available)

- Vessel wall visibility

- Vessel wall thickness

- Contrast enhancement in vessel wall

Secondary outcome

n.a.

Study description

Background summary

Atherosclerosis is an important cause of ischemic stroke. Besides the more widely studied extracranial carotid atherosclerosis, also intracranial atherosclerotic disease (IAD) is an independent risk factor for ischemic stroke.1-3 IAD has recently been found to be much more common in the Caucasian population than previously presumed, highlighting the relevance of adequate diagnostic methods for the condition.4-6
Assessment of intracranial arteries with CTA, MRA or transcranial Doppler (TCD) provides information on the degree of luminal stenosis, but not on the vessel wall. Intracranial vessel wall imaging may enable to determine the underlying

pathology of the intracranial stenosis and thereby make targeted treatment possible. Also, in the case of atherosclerosis, it may enable to visualise plaque burden and composition. That might help to identify a subgroup of IAD patients at the highest risk of stroke and eventually to select patients for specific therapy. High-resolution MRI has already shown capable of accurately visualising the vessel wall in extracranial atherosclerosis. Further, promising results on intracranial vessel wall imaging with 3 Tesla MRI were recently published.7-10 Our aim is to gain experience with intracranial vessel wall MR imaging.

Study objective

the main objective of this study is to evaluate the ability and reproducibility of high-resolution 3 Tesla MR imaging to visualise intracranial arteries and intracranial atherosclerotic disease in patients with previous TIA or ischemic stroke.

Study design

single centre, observational feasibility study

Study burden and risks

The risk of participation to this study is low. MRI is a safe imaging technique without radiation exposure. During the MRI examination patients will have an intravenous line for gadolinium contrast administration. Side effects of the MRI contrast agent are rare and usually harmless.
Individual patients will not benefit from participation in this study. The study will be done in this specific patient group, since patients with previous TIA or ischemic stroke and vascular risk factors are more likely to have IAD than patients without.

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

previous TIA or ischemic stroke
>18 yr
two or more vascular risk factors

Exclusion criteria

standard contra-indications to MRI
modified Rankin score >3
renal clearance <30 ml/min

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):	06-05-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2014
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	NL48064.018.14