Silent MR Angiography (MRA) of intracranial and extracranial carotid arteries.

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Test the optimized MRI sequences/technology against CTA as gold standard, in terms ofimage quality, signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR), speed, and accuracy/reproducibility of extracted quantitative parameters.

Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON43790

Source
ToetsingOnline

Brief title
Silent MRA of carotid arteries

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerotic disease in the carotid artery; wall thickening in the artery

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: GE Healthcare

Intervention

Keyword: carotisbifurcatiion, Ischemic stroke, MRI, Pulse sequences

Outcome measures

Primary outcome

Generally, data will be collected and analysis techniques will be used as

appropriate for the specific project and its purpose. The overall Image quality

the primary outcome parameter.

Secondary outcome

• SNR and CNR (lesion versus background) will be measured.

• Artifacts will be ranked on a five point scale.

Study description

Background summary

Ischemic stroke is mainly due to atherosclerotic disease in the carotid bifurcation. For this reason, all patients with ischemic stroke are evaluated for luminal stenosis in the carotid bifurcation, and carotid endarterectomy is performed in patients with a stenosis with of >70%. Besides the carotid, proximal stenosis at the aortic arch or intracranial stenosis can be the underlying cause of ischemic stroke. There is gradual shift occurring, from focussed evaluation of only the carotid bifurcation (e.g. with duplex ultrasound or (TOF MRA) towards comprehensive evaluation of the supra-aortic arteries from the aortic arch to the intracranial circulation (e.g. CT angiography, CEMRA).

Recently a new sequence is developed. Silent MR techniques based on zero TE technology have the advantage of reducing acoustic noise during acquisition, which improves patient comfort and cooperation. The question still to be answered is whether image quality and accuracy is affected by this new approach. The zero TE approach in combination with a read out that follows a spiral path might also provide additional features for optimization of image quality. For evaluation of atherosclerotic disease in the carotid bifurcation, Zero TE MRI and MRA might reduce motion and flow artifacts which normally hamper accurate evaluation.

CTA and CEMRA require the injection of contrast agents. Silent MRA with ASL preparation might replace CEMRA in the evaluation of the supra-aortic arteries. Both the HNS coils as well as the radiation therapy open head & neck coil suite could be used for signal reception. The performance of the two coils will be compared.
The proposed studies will demonstrate what the additional value is of the Silent MRI in the visualization in patients with known atherosclerotic disease in the carotid bifurcation . The studies will make clear whether the next phase, clinical use of the sequences, is warranted.

Study objective

Test the optimized MRI sequences/technology against CTA as gold standard, in terms of
image quality, signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR), speed, and
accuracy/reproducibility of extracted quantitative parameters.

Study design

Observational diagnostic study

Study burden and risks

MRI scan fora maximum 40 minutes and exposure to acoustic noise. Other than that no major risks for the individual subject.
There are no benefits to the individual subject..
Benefits to the Population: This study will show the value of a new MRI sequence for intracranial coiled aneurysms.

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

* Patients with known atherosclerotic disease in the carotid bifurcation
* At least 18 years old
* Signed informed consent
* No contra-indication to an MRI scan

Exclusion criteria

Subjects with a typical contra-indication to an MRI exam.
Subjects who have a documented allergy to MRI contrast media or a contra-indication for contrast-media are eligible for MRI, but will not undergo contrast-enhanced MRI.
Woman who are pregnant or lactating
Having any physical or mental status that interferes with the informed consent procedure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-11-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-04-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL51826.078.15