Silent MRA of intracranial arteries: follow-up of aneurysms treated with coils

Published: 12-12-2014
Last updated: 21-04-2024

Test the optimized MRI sequences/technology against commercially-available, clinical MRIsequences in terms of image quality, signal-to-noise ratio (SNR), contrast-to-noise ratio(CNR), speed, and accuracy/reproducibility of extracted quantitative...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

Summary

ID

NL-OMON40976

Source
ToetsingOnline

Brief title
Silent MRA of intracranial arteries

Condition

- Aneurysms and artery dissections

Synonym
Vessel dilation

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: Aneurysms, MRi, Pulse sequences

Outcome measures

Primary outcome

Outcome measure: image quality (score 1-5), CNR, artefacts. Comparison of the

diagnostic evaluation of the three MRA techniques (blinded evaluation).

Diagnostic accuracy of TOF MRA and Silent MRA with CEMRA as gold standard.

Secondary outcome

na

Study description

Background summary

Intracranial aneurysms are currently treated with endovascular techniques like coiling and stenting. After treatment, imaging is required to demonstrate that the aneurysm has been excluded from the circulation. Current imaging strategies include TOF MRA as the first modality for evaluation. Spin dephasing and saturation constitute major limitations of 3D TOF-MRA; these might influence the detection and evaluation of residual aneurysmal pouches. Contrast-enhanced MRA (CE-MRA) has been used to increase signal intensity in residual pouches; however, venous enhancement often degrades image quality

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 endpoints following a spiral path might also provide additional features for optimization of image quality. For evaluation of intracranial arteries and of atherosclerotic disease in the carotid bifurcation, Zero TE MRI and MRA might reduce motion and flow artifacts which normally hamper accurate evaluation.

TOF MRA is dependent on flow, which may mean that recanalisation of a coiled aneurysm is not visualised with this protocol. Spin dephasing due to circular flow in aneurysmal remnants is absent in the zero TE approach. CEMRA requires

the injection of contrast agents. Both sequences produce acoustic noise. Silent MRA with ASL preparation might replace TOF MRA and CEMRA in the follow-up of patients with coiled aneurysms.

The proposed studies will demonstrate what the additional value is of the Silent MRI in the visualization in patients treated with coils. 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 commercially-available, clinical MRI
sequences 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

1. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Burden: MRI extension for maximum 40 minutes and exposure to acoustic noise.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients treated with coils for an intracranial aneurysm
Scheduled MRI scan
At least 18 years old
Signed informed consent
No contra-indication to an MRI scan

Exclusion criteria

Not yet 18 years old
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:	Recruiting
Start date (anticipated):	12-05-2015
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2014
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	NL49343.078.14