Arterial spin labeling MRI in the follow-up of therapeutic internal carotid artery occlusion

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- To assess the number of de novo aneurysms in patients who underwent therapeutic ICA occlusion more than 5years ago.- To assess infarct load in patients who underwent therapeutic ICA occlusion more than 5 years ago.- To evaluate the distribution of...

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

Summary

ID

NL-OMON32523

Source
ToetsingOnline

Brief title
AMeRICA

Condition

- Central nervous system vascular disorders
- Aneurysms and artery dissections

Synonym
intracranial aneurysm, vascular dilatation in the brain

Research involving
Human

Sponsors and support

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

fonds;hersenstichting

Intervention

Keyword: ASL, Infarction, Intracranial aneurysm, Therapeutic ICA occlusion

Outcome measures

Primary outcome

- De novo aneurysms on magnetic resonance angiography (MRA)

- Whole brain and regional CBF (ml/100 grams/min)

Secondary outcome

- Infarction on T2-weighted MRI and Fluid Attenuated Inversion Recovery (FLAIR)

Study description

Background summary

Large (>10 mm) and giant (>25 mm) symptomatic internal carotid artery (ICA) aneurysms are treated by occlusion of the ICA if tolerated. The long-term effect of this treatment remains unclear. With only one patent ICA, it is possible that patients develop a delay in or lack of perfusion on the side of the ICA occlusion, suffer from more (subclinical) infarctions caused by lower regional perfusion, or develop new intracranial aneurysms by the change in hemodynamics. Arterial Spin Labeling (ASL) is a relatively new and non-invasive magnetic resonance imaging (MRI) technique for the visualisation and quantification of cerebral perfusion.
Using selective ASL it is also possible to image the flow territories of the major brain feeding arteries independently (the internal carotid arteries and the basilar artery).

Study objective

- To assess the number of de novo aneurysms in patients who underwent therapeutic ICA occlusion more than 5
years ago.
- To assess infarct load in patients who underwent therapeutic ICA occlusion more than 5 years ago.
- To evaluate the distribution of cerebral perfusion over the left and right hemisphere in patients who underwent therapeutic ICA occlusion more than 5

years ago.

Study design

Follow-up cohort study

Study burden and risks

This study is conducted using a non-invasive imaging modality: MRI. There is no risk associated with participation. If abnormalities on the MR images are apparent, a specialist will be consulted.

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

Therapeutic ICA occlusion in Tilburg or Amsterdam between January 1996 and August 2004

Exclusion criteria

The presence of metal in the body (e.g. osteosynthetic material, pacemaker, artificial cardiac valves); claustrophobia; surgery performed in the area of measurement with the use of neurosurgical clips.

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):	01-11-2009
Enrollment:	44
Type:	Anticipated

Ethics review

Approved WMO

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	NL30217.018.09