3- and 7 Tesla MRI for detection of changes in white matter, cerebral perfusion and micro-/and macrovascular structures after revascularization of the carotid artery

Published: 11-06-2018
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To investigate the development of white matter lesions, changes in cerebral perfusion and cerebral vascular structures on 3T and 7T MRI following carotid revascularization

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON50680

Source
ToetsingOnline

Brief title
Carotis 7T Study

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
carotid artery atherosclerosis, carotid artery stenosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 7T, Carotid, DWI, MRI

Outcome measures

Primary outcome

white matter lesions, cerebral perfusion on 3T and 7T MRI.

Secondary outcome

Cerebrovascular structures on 3T/7T MRI. Micro-embolic signals and MCA-flow velocity on TCD. Number and type of events after intervention (stroke, TIA, cardiac event, IC-admission) and modified Rankin Scale (mRS).

Study description

Background summary

10-15% of all strokes are caused by atherosclerotic stenosis of the internal carotid artery. Carotid endarterectomy (CEA) and carotid artery stenting (CAS) have been proven to reduce the long-term risk of stroke in patients with symptomatic carotid artery stenosis. Unfortunately, this procedure is known to be associated with serious periprocedural adverse events, occurring in up to 5% of patients. The occurrence of postprocedural incidence of new diffusion weighted imaging (DWI) lesion is relatively high in both CAS patients (50%) and CEA patients (17%). These white matter lesions, with or without corresponding focal deficits, may lead to clinically relevant future events such as cognitive decline, dementia and increased risk of future cerebrovascular events. In this study we aim to investigate changes on MR imaging of the brain as a result of carotid artery endarterectomy or stenting. We intend to identify small and large vessel characteristics as well as cerebral perfusion for prediction of development of perioperative ischemic lesions on both 3T and 7T MRI.

Study objective

To investigate the development of white matter lesions, changes in cerebral perfusion and cerebral vascular structures on 3T and 7T MRI following carotid revascularization

Study design

Monocenter prospective observational study

Study burden and risks

The potential benefit for the enrolled patients is small except that these patients will be monitored more closely than usual by MRI scans that will be clinically evaluated for insidious pathology. Benefits in term of knowledge are potentially very valuable as the study findings will substantially improve our understanding of the risk of post-procedural complications. Risks are small since there are no know risks associated with MRI acquisition.

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

Carotid artery stenosis
Deemed to require treatment (carotid endarterectomy or carotid artery stenting) by the multidisciplary panel

Exclusion criteria

Contra-indication for MRI
Age<18 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-11-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2018
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	26-02-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-04-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL63925.041.18