Seeking the link between extracranial carotid artery aneurysms and small vessel disease

Published: 14-09-2022 Last updated: 21-09-2024

To assess the presence of small vessel disease (i.e. WMHs, lacunes, microbleeds, perivascular spaces, and recent small subcortical infarcts) based on 3 tesla brain and carotid MRI in patients with ECAA.

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

Summary

ID

NL-OMON51931

Source ToetsingOnline

Brief title ECAA Brain MRI

Condition

• Aneurysms and artery dissections

Synonym dilated carotid artery, extracraniel carotid aneurysm

Research involving

Human

Sponsors and support

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

1 - Seeking the link between extracranial carotid artery aneurysms and small vessel ... 12-05-2025

Intervention

Keyword: 3T, Aneurysm, Carotid, SVD

Outcome measures

Primary outcome

Presence of small vessel disease (i.e. WMH, lacunes, microbleeds, perivascular spaces, and recent small subcortical infarcts)) on 3 tesla brain MRI in ECAA patients measured by number, volume and localization.

Secondary outcome

- Progression of smalle vessel disease over time
- Small vessel disease related brain imaging features on brain MRI related to

carotid aneurysm size (maximum diameter) based on previous CT/MRI imaging

- Silent brain infarcts on brain MRI measured by number, volume and localization
- Pulsatility and distensibility of the carotid wall

Study description

Background summary

Extracranial carotid artery aneurysms (ECAA*s) are rare. Because of the rarity of this disease, no treatment guidelines exist. In order to understand which ECAA patients benefit from medical therapy, more should be known about the possible outcomes of this disease. Small vessel disease seen on brain MRI*s could be a good marker to assess possible silent cerebrovascular disease caused by ECAA*s, suggesting underlying generalized vascular disease. With this knowledge, medical therapy for ECAA patients can be optimized to treat possible generalized vascular disease, aiding physicians in choosing a treatment strategy.

Study objective

To assess the presence of small vessel disease (i.e. WMHs, lacunes, microbleeds, perivascular spaces, and recent small subcortical infarcts) based

2 - Seeking the link between extracranial carotid artery aneurysms and small vessel ... 12-05-2025

on 3 tesla brain and carotid MRI in patients with ECAA.

Study design

Monocenter longitudinal observational cohort study with 2 years of follow-up.

Study burden and risks

The burden associated with participation is that the ECAA patients will come the UMCU every two years to receive a brain MRI. If possible, these visits will be scheduled with the regular visits with their vascular surgeon. The data and brain MRIs from the control group will be taken from the Rotterdam study. There is no direct personal benefit for the enrolled patients or controls except that the ECAA patients will be monitored more closely than usual by MRI scans that will be clinically evaluated for insidious disease. Benefits in term of knowledge are potentially very valuable as the study findings will improve our understanding of the risk of brain damage by ECAA. Risks are small since there are no known risks associated with MRI acquisition.

Contacts

Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100 Utrecht 3584 CX NL **Scientific** Universitair Medisch Centrum Utrecht

Heidelberglaan 100 Utrecht 3584 CX NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Extracranial carotis artery aneurysm

Exclusion criteria

Contra-indication for MRI Age <18 years

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):	25-03-2023
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:

14-09-2022

Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-11-2022
Application type:	Amendment
Review commission:	METC NedMec

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 CCMO **ID** NL78589.041.21