# Imaging of extracranial carotid aneurysms

Published: 13-09-2016 Last updated: 17-04-2024

The primary objective of this study is to observe if there are differences in diameter measurements of 3T MRI and CTA at baseline and 1 year after baseline measured by two independent observers (radiologist) blinded for previous imaging. The...

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

# Summary

### ID

NL-OMON43210

**Source** ToetsingOnline

Brief title ECAA imaging

## Condition

• Aneurysms and artery dissections

#### Synonym

dilatation of the extracranial carotid artery, expansion of the neck artery

#### **Research involving** Human

Human

### **Sponsors and support**

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

### Intervention

Keyword: 3 tesla MRI, CTA, Extracranial Carotid Artery Aneurysm

### **Outcome measures**

#### **Primary outcome**

Observational study: differences in diameter measurements using 3T MRI and CTA will be assed.

#### Secondary outcome

- The inter-rater reliability and intra-observer agreement of volume measurement in ECAA using CTA with 3D reconstruction at baseline and 1 year after baseline measured by two independent observers blinded for previous imaging.

- Aneurysm diameter growth (defined as at least 3mm growth in largest diameter

of the aneurysm) on 3T MRI between baseline and 1 year after baseline measured

by two independent observers blinded for previous imaging.

- Degree of gadolium enhancement in the ECAA wall on 3T MRI (categorized into

no, moderate or severe enhancements). 3T MRI will be read by two independent

observers blinded for patient data and previous imaging.

- Correlation between gadolium enhancement and aneurysm growth on 3T MRI.
- Prevalence of white matter abnormalities on 3T MRI.

# **Study description**

### **Background summary**

Extracranial carotid artery aneurysms (ECAAs) are very rare, but exact data on the incidence are lacking. Current literature is limited to case reports and small case series with incomplete data and lacking long-term follow-up.

Presentation is usually around the age of 60, dependent on the etiology, which is divers and ranges from atherosclerosis, infection, fibromuscular dysplasia, to traumatic or spontaneous dissection.

Most ECAAs are found by coincidence in asymptomatic patients during imaging of the brain or cervical vertebrae.

When symptomatic, cerebral thrombo-embolism and local compression seem most frequent, while the risk of ECAA rupture, although a feared complication seems ignorable small. Local compression may lead to peripheral neurological dysfunction of the cranial nerves or dysphagia.

At all stages, the purpose of (additional) imaging is to 1) confirm diagnosis; 2) classify the ECAA; 3) to assess the anatomy in order to plan surgical or endovascular treatment; and 4) follow up of aneurysm growth over time. Most aneurysms are diagnosed by using echo/duplex ultrasound imaging (DUS), but computed tomography angiography (CTA) seem more accurate and is usually done additionally to confirm the diagnosis. Angiography with CTA visualizes the lumen of the carotid artery, however aneurysm changes and rupture occur in the vessel wall.

A growing body of evidence has supported the role of aneurysm wall inflammation in the formation, progression and rupture of intracranial aneurysms. In a histologic analysis of ECAA two distinct types of aneurysms have been found, degenerative and dissecting aneurysms. In some of the degenerative aneurysms different types of inflammatory cells have been found.

Vessel wall imaging was recently made possible, for instance with 3Tesla contrast-enhanced MRI (3T MRI). It is postulated that administration of gadolinium during MRI results in enhancements of sites with inflammation, which could eventually be a marker for aneurysm growth.

Another technique that can contribute to the diagnostic and therapeutic work-up is CTA with 3-dimensional (3D) reconstructions. Different methods of measurement of an aneurysm size have been applied, however measurement of the diameter appears to be unreliable in aneurysms located elsewhere in the body, with low inter- and intra-observer reliability. A recent study in abdominal aortic aneurysms showed measurement of aneurysm sac volume, which are more precise than diameter measurement, can be of additional value. This study showed that sac volume changes are not detected in diameter measurements and also aneurysm diameters can change without changing the total volume of the aneurysm indicating morphological changes of an aneurysm.

Because the rarity of ECAA little is known about the natural course of both asymptomatic and symptomatic ECAA. We developed this protocol to gain more insight in aneurysm wall changes and growth to possibly be able to predict the clinical course of an ECCA. This way the treatment can be started before any devastating symptoms occur.

### Study objective

The primary objective of this study is to observe if there are differences in diameter measurements of 3T MRI and CTA at baseline and 1 year after baseline

measured by two independent observers (radiologist) blinded for previous imaging.

The secondary objectives are to a) assess the feasibility of volume measurement in ECAA using CTA with 3D reconstruction, b) to assess the reliability of diameter and volume measurement in determining growth in an ECAA, c) assess prevalence of gadolium enhancement in the ECAA wall, d) investigate if growth rate is higher in aneurysms with wall enhancement on 3T MRI compared to aneurysms without enhancement and e) whether white matter abnormalities are seen due to micro-embolism even though patients are asymptomatic.

### Study design

This is a pilot study

### Study burden and risks

Participation in this study takes some time but carry little risks. Patienst will get an IV-catheter for Gadolinium administration during the MRI scan. Very few people (less then 2.5%) that undergo a contrast enhanced MRI experience side effect of the contrast agent. These side effects are usualy mild. Severe side effects are extremly rare.

# 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**

Dutch patient registered in the carotid aneurysm registry Willingness and ability to participate in all scheduled procedures outlined in the protocol. Written informed consent

## **Exclusion criteria**

1. Subject registered in the CAR that have undergone surgical or endovascular treatment of the ECAA.

2. Patients with contraindications for CTA such as:

1) severe renal insufficiency (GFR<30ml/min/ 1.73m2) or nephrogenic systemic

fibrosis/nephrogenic fibrosing nephropathy; 2) contrast allergy, and 3) pregnancy.

3. Contraindications for 3T MRI, such as 1) pacemaker or metal object in or around the body;

2)claustrophobia, 3) severe renal insufficiency (GFR<30ml/min/ 1.73m2) or nephrogenic systemic fibrosis / nephrogenic fibrosing nephropathy; and 4) pregnancy.

# Study design

## Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2017
Enrollment:	15

5 - Imaging of extracranial carotid aneurysms 13-05-2025

Type:

#### Actual

Ethics review	
Approved WMO Date:	13-09-2016
Application type:	First submission
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 CCMO **ID** NL56734.041.16