# Non-invasive MR imaging of vulnerable carotid artery plaque characteristics

Published: 07-06-2017 Last updated: 13-04-2024

The objective is to study reproducibility of the assessment of repetitive plaque deformation during the cardiac cycle in the carotid arteries by using advanced MRI techniques and state-of-the-art hardware.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

# Summary

#### ID

NL-OMON49132

**Source** ToetsingOnline

**Brief title** MR imaging of carotid artery plaque deformation

# Condition

• Arteriosclerosis, stenosis, vascular insufficiency and necrosis

#### Synonym

arteriosclerosis, atherosclerotic plaque, inflammation in the vessel wall

#### **Research involving** Human

## **Sponsors and support**

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht **Source(s) of monetary or material Support:** Stichting de Weijerhorst

## Intervention

Keyword: Atherosclerosis, Carotid, Deformation, MRI

#### **Outcome measures**

#### **Primary outcome**

To assess reproducibility of the new MRI techniques acquiring carotid artery

plaque deformation during the cardiac cycle.

#### Secondary outcome

To correlate plaque deformation with plaque components that are most likely

apparent in (vulnerable) atherosclerotic plaques (e.g. lipid-rich necrotic

core, fibrous cap, calcifications and fibrous tissue)

# **Study description**

#### **Background summary**

Magnetic Resonance Imaging (MRI) is a non-invasive imaging technique with high soft tissue contrast and therefore the perfect non-invasive image modality to visualize plague composition and deformation. While imaging of plague composition is already well established, imaging of plague deformation is far more challenging because of the need for a high spatial resolution (in order to visualise the various plaque components in the atherosclerotic plaque) together with a high temporal resolution (in order to visualise different time phases within the cardiac cycle. Recently, a new state-of-the-art MRI system has been installed in our department and dedicated 32-channel carotid receiver coil has been ordered to obtain a high MR signal of the carotid arteries in order to meet these requisites. Our group has extensive experience in imaging various aspects of atherosclerotic plaque, like its composition (using multi-contrast sequences) and microvasculature (using dynamic contrast enhanced sequences). By using this new advanced MRI equipment, we hypothesize that Magnetic Resonance Imaging (MRI) is able to visualize the repetitive plaque deformation within the cardiac cycle in the carotid arteries.

#### **Study objective**

The objective is to study reproducibility of the assessment of repetitive

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plaque deformation during the cardiac cycle in the carotid arteries by using advanced MRI techniques and state-of-the-art hardware.

#### Study design

This study is designed as a prospective observational feasibility study. First, 15 healthy volunteers and 10 patients (known with carotid atherosclerotic lesions of at least 2 mm thick and causing 30-99% stenosis [ECST measure]) will undergo an MRI exam for the development and optimization of the new MRI techniques. Second, 20 patients that are known with carotid atherosclerotic lesions of at least 2 mm thick and causing 30-99% stenosis will undergo an MRI exam to assess reproducibility of the new techniques and relate plaque deformation to plaque composition. All MRI examinations will take place at the Maastricht University Medical Centre+ (MUMC+).

#### Study burden and risks

All volunteers and patients will be subjected to an MRI exam where a standard gadolinium-based contrast agent will be administered to the patients (not in the healthy volunteers!). All subjects will be accurately screened for MRI contraindications. With extensive screening for MRI contraindications, there are only minimal risks associated with an MRI examination. These risks include (1) heating of the patient by extensive use of RF pulses, (2) hearing damage by the loud noises (3) peripheral nerve stimulation by the rapid switching of magnetic gradients, (4) local burns, and contrast reactions. These risks are minimized by the use of hearing protection, covering bare skin to avoid direct contact with the coil wiring, and remaining within safety levels for the gradient switching and RF pulses. Assessing the patients\* kidney function, using the glomerular filtration rate, minimizes the risk of a contrast reaction. Patients with an estimated glomerular filtration rate (GFR) \* 60 mL/min/1,73m2) or known allergy to gadolinium-based contrast agents will be excluded. The custom-build, dedicated receiver coil that will be used in this study, is a receiver-only coil that is fully decoupled during RF transmission, i.e. the coil is only used to receive the MRI signal, and therefore does not impose additional risks. As this custom-made coil, developed and built by MR Coils (Utrecht, NL), is currently a one-off model, it lacks CE certification. The Medical Instrumentation and Information Technology (MIT) department of the Maastricht UMC+ is already working on the intake procedures. We would like to emphasize that we will not investigate the performance of this coil, as we will only use the coil for signal detection during MRI examinations. We already performed an extensive risk analysis with the Medical Instrumentation Technology department at the MUMC+. This risk analysis showed that the use of this coil does not impose any additional risks to the patients compared to when using a commercial Philips coil. In fact, Philips Healthcare delivers crucial components to the manufacturer of the coils (MR Coils BV). Study results are expected to contribute to improvement of vulnerable plaque detection for future

patients.

# Contacts

#### Public

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

## **Inclusion criteria**

\* Patients only: Known with an atherosclerotic lesion in (one of) the carotid arteries of at least 2 mm thick causing 30-99% stenosis [ECST guideline \* Healthy volunteer only: Should consider himself/herself as 'healthy' and not known with any major cardiovascular diseases

## **Exclusion criteria**

\* MRI contraindications

# Study design

# Design

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

## Recruitment

ML

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2018
Enrollment:	45
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	07-06-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

# **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

ССМО

**ID** NL60524.068.17