# MRI-derived Virtual Histology: Atherosclerotic Plaque Morphology in Relation to End-Organ Damage

Published: 22-06-2010 Last updated: 02-05-2024

- To detect carotid and aortic plaque morphology and long term plaque behaviour in patients with cerebral and cardiac end-organ damage (NSTEMI / STEMI and TIA / CVA) with 1.5T MRI-derived virtual histology and relation to biomarkers.- To correlate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

# Summary

### ID

NL-OMON34848

**Source** ToetsingOnline

**Brief title** Plaque Morphology in Relation to End-Organ Damage

### Condition

- Coronary artery disorders
- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym atheroslcerosis

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: Hartziekten

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#### Source(s) of monetary or material Support: ICIN

### Intervention

Keyword: atheroclerotic plaque, end-organ damage, histology, MRI

### **Outcome measures**

#### **Primary outcome**

- Comparison MRI based virtual histology of atherosclerotic plaques between

patient groups and plaque behaviour over time.

#### Secondary outcome

- Correlation between CEA specimen and MRI based virtual histology of carotid

plaque.

- Relation of biomarkers to plaque morphology and longitudinal behavior
- Feasibility testing of new high field MRI-sequences for

high-spatial-resolution vessel wall imaging of the aorta, carotid artery and

coronary arteries.

# **Study description**

#### **Background summary**

- Acute coronary and cerebral vascular syndromes are caused by thrombus formation in moderately stenosed arteries at the site of a ruptured or eroded fibrous cap. Different atherosclerotic plaque morphology is suggested in non-ST-elevation myocardial infarction (NSTEMI) versus ST-elevation myocardial infarction (STEMI) and for Transient Ischemic Attack (TIA) versus Cerebro Vascular Accident (CVA). It has also been suggested that TIA related plaques show prolonged plaque instability compared to CVA related plaques. However, these observations are based on limited data and validation to histological specimen is scarce.

- Although, NSTEMI / STEMI and TIA / CVA have different end organs (heart and brain respectively) comparable plaque morphology in coronary artery, aorta and

carotid artery and behaviour over time has been suggested.

- Magnetic Resonance Imaging (MRI) based virtual histology has the potential to investigate the atherosclerosis in different larger vascular territories (i.e. aorta, carotid) and to determine cerebral end organ damage in a non-invasive fashion.

- Magnetic Resonance Imaging (MRI) based virtual histology at 1,5 Tesla is not sufficient to determine plaque morphology in smaller vascular territories. However, high field MRI (3T and 7T) bears the potential to assess plaque morphology in smaller vascular territories such as the coronary arteries. This enables further exploration of coronary atherosclerotic plaques and the relation between plaques in different territories and end organs.

#### **Study objective**

- To detect carotid and aortic plaque morphology and long term plaque behaviour in patients with cerebral and cardiac end-organ damage (NSTEMI / STEMI and TIA / CVA) with 1.5T MRI-derived virtual histology and relation to biomarkers.

- To correlate MRI atherosclerotic plaque virtual histology to histologic specimen obtained in subgroup of patients undergoing CEA.

- To investigate plaque morphology and relation to cerebral end organ damage.

- To develop new high field MRI-sequences for high-spatial-resolution vessel wall imaging of the aorta, carotid artery and coronary arteries to further explore the relation between plaques in different territories and their end organs.

#### Study design

- MRI vessel wall aortic arch, carotid arteries, and MRI cerebrum at baseline and follow up (1 year).

- Histological assessment of Carotid End Arterectomy (CEA) specimen in subgroup of patients undergoing CEA and correlation to MRI virtual histology.

- Baseline and follow up levels of biomarkers.

- Development of high field vessel wall imaging sequences

#### Study burden and risks

- When exclusion criteria are fulfilled the MRI is not harmful.

- For the patient there is no direct benefit related to participation.

# Contacts

**Public** Selecteer

Postbus 9600 2300 RC Leiden NL **Scientific** Selecteer

Postbus 9600 2300 RC Leiden NL

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

### **Inclusion criteria**

Patients with recent ( < 2 weeks) Cerebro Vascular Accident (CVA), Transient Ischemic Attack, ST-elevation Myocardial Infarction (STEMI), Non-ST-elevation Myocardial Infarction (NSTEMI)

## **Exclusion criteria**

Contradication for MRI or Gadolinium based contrast agent

# Study design

## Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010
Enrollment:	400
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	22-06-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

# **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.

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# In other registers

### Register

ССМО

**ID** NL31244.058.10