# Study To Evaluate the reproducibility of non-invasive Plaque lipid content measurements in-vivo in humans, by means of magnetic resonance Spectroscopy.

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The primary aim of this study is to assess reproducibility of carotid artery plaque lipid content by means of magnetic resonance spectroscopy (MRS).

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

# Summary

### ID

NL-OMON31955

**Source** ToetsingOnline

Brief title STEPS

# Condition

• Arteriosclerosis, stenosis, vascular insufficiency and necrosis

#### Synonym

atherosclerosis, cardiovascular disease

### **Research involving**

Human

### **Sponsors and support**

**Primary sponsor:** Academisch Medisch Centrum **Source(s) of monetary or material Support:** afdelings budget.

### Intervention

Keyword: Atherosclerosis, Cardiovascular disease risk, Magnetic Resonance Spectroscopy

### **Outcome measures**

#### **Primary outcome**

The ratio of the integrated lipid peak versus the unsuppressed water peak,

expressed as a percentage, measured by MRS.

#### Secondary outcome

# **Study description**

#### **Background summary**

Atherosclerosis is a protracted and in fact lifelong progressive disease. Over time, lipids accumulate in the artery wall forming fatty streaks, which eventually can develop into atherosclerotic plaques1. The transformation of a quiescent atherosclerotic plaque to an active plaque leads to acute vascular events, such as myocardial infarction and stroke1.

In an attempt to gear down the pandemic of cardiovascular disease, much effort has been put in the development of novel cardiovascular drugs, with the main focus on prevention. In the development of preventive pharmacotherapy, Low Density Lipoprotein cholesterol (LDL-C) lowering drugs played a pivotal role. The hypothesis that serum lipid lowering results in decrease of lipid accumulation in the arterial wall and thus atherogenesis, has formed the basis for this drug developing strategy1, 2.

To draw valid conclusions about the determinants of the effectiveness of lipid altering therapeutic interventions, imaging of atherosclerosis can be used as a surrogate marker for the assessment of efficacy of a novel compound3. Although imaging arterial wall dimensions by B-mode ultrasound, intravascular ultrasound and magnetic resonance imaging have proved to be of great use, the effects of cardiovascular drugs on vascular wall composition remains unclear. Magnetic resonance spectroscopy (MRS) is a non-invasive imaging modality that gives a spectrum of resonances, affording detection of specific chemical components through their inherent frequency shift relative to water4. In image guided MRS, an MR image can be utilized to image and localize a plaque. Proton spectra can then be collected from these plaques, such that the specific proton resonances of lipid components in a mobile state, including cholesterol ester (CE), can be identified5.

The aim of this study is to develop non-invasive spectroscopy approaches that will quantify the lipid content of plaques and will have the potential for repeated in vivo measurements. Therefore, we intend to study the reproducibility of plaque lipid content measurements by MRS in subjects that are known to have carotid artery plaques.

#### **Study objective**

The primary aim of this study is to assess reproducibility of carotid artery plaque lipid content by means of magnetic resonance spectroscopy (MRS).

#### Study design

Reproducibility study, using non-invasive MRS.

#### Study burden and risks

None.

# Contacts

**Public** Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Nederland **Scientific** Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Nederland

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

### **Inclusion criteria**

More than 40% carotid artery stenosis on ultrasound duplex.

### **Exclusion criteria**

- Any contraindications for MRI.
- Subjects that will go for endarterectomy.

# Study design

# Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	21-02-2008
Enrollment:	15
Туре:	Anticipated

# **Ethics review**

Approved WMO Application type: Review commission:

First submission METC Amsterdam UMC

# **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** NL21657.018.08