Assessment of atherosclerosis with 3 Tesla Magnetic Resonance Imaging: prevalence, progression and prognosis

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON38194

Source
ToetsingOnline

Brief title
Assessment of atherosclerosis with 3T MRI

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis, vessel wall atheroma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 3T MRI, aorta, atherosclerosis, coronary arteries

Outcome measures

Primary outcome

1 .Prevalence and distribution of coronary and aortic atherosclerosis

The prevalence of atherosclerosis is defined as the total number of atherosclerotic lesions in the coronary arteries and aorta on the baseline 3T MRI scan.

2. Progression (rate of changes) in coronary and aortic atherosclerosis

Progression in atherosclerosis can express itself as an increase in the total number of atherosclerotic lesions, geometric measures or the proportion of the vessel wall area occupied by various plaque components. In this study all three variables of atherosclerosis will be used to assess the progression of atherosclerosis.

3. Coronary and aortic atherosclerosis to predict future events

The baseline MRI scan will be used to predict future events. With respect to future events, information will be collected concerning non fatal and fatal vascular disease with clear definition.

Secondary outcome

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Study description

Background summary

Despite considerable progress over last decades, cardiovascular disease remains the leading cause of morbidity and mortality worldwide with the most serious outcome being myocardial infarction, stroke and death. Magnetic Resonance Imaging (MRI) is one of the imaging techniques that can detect atherosclerotic lesions that are present years before a symptomatic cardiovascular events occurs. Yet, little is known about the prevalence and distribution of aortic and coronary atherosclerosis in patients with symptoms of non-coronary origin. Furthermore, before the use in clinic practice the incremental predictive value of coronary and aortic 3 Tesla MRI in predicting future cardiovascular events over current used methods to assess risk has to be established.

Study objective

The aims of the study are the following:

1. to study the prevalence of coronary and aortic atherosclerosis assessed using 3 Tesla MRI
2. to study rate of change in coronary and aortic atherosclerosis measurements assessed using 3 Tesla MR imaging
3. to study the ability of coronary and aortic atherosclerosis to predict future events on top of established risk prediction models

Study design

The study is designed as a single center cohort study with a cross-sectional and a longitudinal part with repeated MRI scans and event follow up. The MRI scans will be performed on a 3 Tesla MRI with a state of the art MRI protocol. In 24 months all patients will undergo four MRI scan of the coronary arteries and the aorta. The baseline MRI scan will be used to assess the prevalence and distribution of atherosclerosis. The baseline MRI scan combined with the clinical follow-up will determine the predictive value of the various MRI-derived plaque volumes. The MRI scans at 6, 12 and 24 months will be used to study the rate of changes in coronary and aortic MRI-derived plaque volumes.

Study burden and risks

Magnetic Resonance Imaging has the advantage of not using and is able to image atherosclerotic plaque components. For any risks associated with the use of contrast (gadolinium) all necessary precaution will be taken (see E7/E9). In two years, all patients will undergo four MRI scans of the coronary arteries

and aorta. This extent of burden and the minimal risks of participation is justified given the importance of improved diagnosis in patients with atherosclerosis and the possibility of improved diagnosis and treatment in the future.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 AA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 AA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 years or older
- Patients with coronary artery disease, Transient Ischemic Attack (TIA), minor ischemic stroke, abdominal aortic aneurysm, peripheral arterial disease, presenting with symptoms suggestive of an acute coronary syndrome (ACS) and asymptomatic patients with an increased cardiovascular risk.

Exclusion criteria

- pregnancy or possible pregnancy
- documented allergic reaction to godalinium
- patients with impaired renal fuction (GFR < 30ml/min/1.73m2)
- impossibility to undergo MRI (determined by using the standard contradictions for MR imaging as used for clinical purposes)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO Date:	07-03-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-11-2012
Application type:	Amendment
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	ID
CCMO	NL31637.041.11