Accuracy of 7T contrast-enhanced Magnetic Resonance Angiography for the assessment of coronary artery stenoses: a pilot study

Published: 29-04-2013
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The objective of this study is to assess the diagnostic performance of Ultra-high field 7 Tesla (T) MRA to detect significant coronary stenoses.

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

Summary

ID

NL-OMON41333

Source
ToetsingOnline

Brief title
Accuracy of 7T CE-MRA: a pilot study

Condition

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

Synonym
atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atherosclerosis, coronary arteries, MRA

Outcome measures

Primary outcome

The presence of significant narrowing of the coronary arteries (>50% reduction in diameter) on 7T CE-MRA. The conventional CAG or CT scan will be used as reference standard. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy per patient, vessel, and segment analysis will be calculated with a 95% confidence interval (CI).

Secondary outcome

not applicable

Study description

Background summary

Cardiovascular disease is the leading cause of morbidity and mortality worldwide. Contrast Enhanced Magnetic Resonance Angiography (CE-MRA) is able to visualize the coronary arteries in a non-invasive way. The use of Ultra-high field CE-MRA may increase the diagnostic performance to detect significant coronary artery stenoses.

Study objective

The objective of this study is to assess the diagnostic performance of Ultra-high field 7 Tesla (T) MRA to detect significant coronary stenoses.

Study design

This study is designed as a cross-sectional diagnostic study.

Study burden and risks

There are minimal risks regarding the use of gadolinium contrast. All participants will be screened on allergy for contrast agents and the renal function will be evaluated.
Furthermore, no short or long term adverse effects of the MRI scanners on the human body are known.

Contacts

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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 scheduled for CAG or Computed Tomography to visualize the coronary arteries
- 18 years or older

- written informed consent

Exclusion criteria

- acute coronary syndrome
- atrial fibrillation
- pregnancy or possible pregnancy
- lactation
- documented allergic reaction to gadolinium
- subjects with impaired renal function (severe renal insufficiency, GFR < 30 ml/min/1.73m2)
- impossibility to undergo a MRI scan (determined by using the standard contraindications for MR imaging as used for clinical purposes)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	29-04-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-10-2013

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-12-2015
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	NL42681.041.12