Optimization of a new 3 Tesla Magnetic Resonance Imaging protocol to vizualize the coronary arteries and aorta

Published: 20-09-2010
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Optimization of a recently developed 3T MRI protocol for imaging of the coronary and aortic vessel wall.

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

Summary

ID

NL-OMON36337

Source
ToetsingOnline

Brief title
Vessel wall imaging with 3T MRI

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: 3 Tesla MRI, aorta, atherosclerosis, coronary arteries

Outcome measures

Primary outcome

1. Image quality: subjective and objective

2. Geometric measurement: vessel wall thickness, vessel wall area and lumen area

3. Reproducibility: intra- and interobserver agreement and interscan

reproducibility

Secondary outcome

not applicable

Study description

Background summary

Cardiovascular disease is the leading cause of morbidity and mortality worldwide. The majority of vascular patients die from coronary atherosclerosis rather than from extra coronary atherosclerosis. Therefore, it is important to detect atherosclerosis in the coronary arteries and the aorta at an early stage.

Study objective

Optimization of a recently developed 3T MRI protocol for imaging of the coronary and aortic vessel wall.

Study design

The study is designed as a cross-sectional study. Subjects will undergo two MRI scans in a period of four weeks. Subjects will undergo a 3T MRI scan of the coronary and aortic vessel wall. To enhance the contrast between the vessel wall and the surrounding tissue gadolinium contrast will be used. During the study MRI parameters will be changed to yield the best possible image quality and reproducibility.

Study burden and risks

There are minimal risks regarding the use of gadoliumn contrast. All healthy volunteers will be screened on allergy for contrastagents and the renal function will be assessed.
Furthermore, no short and long term adverse effects of the 3 T MRI scanner 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

- healthy volunteers
- male or female

- 18 years or older

Exclusion criteria

- pregnancy or possible pregnancy
- lactation
- documented allergic reaction to gadolinium
- renal function below normal (GFR < 80ml/min/1.73m2)
- impossibility to undergo MRI (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:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	20-09-2010
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	27-05-2011

Application type:	Amendment
Review commission:	METC NedMec

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	NL32696.041.10