Optimalization of a new 3 tesla Magnetic Resonance Imaging protocol to visualize the aorta

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optimization of a new 3 Tesla Magnetic Resonance Imaging protocol for imaging of the aortic vessel wall in order to enhance the identification of individuals at highest risk of developing clinically manifest atherosclerosis

Ethical review	Approved WMO
Status	Will not start
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON41123

Source
ToetsingOnline

Brief title
Vessel wall imaging with 3T MRI (OPTIMA 2 study)

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atheroslerosis

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

Outcome measures

Primary outcome

1) inter scan reproducibility, in comparison to existing methods

2) acquisition time in comparison to current scanning protocol

3) comparability of vascular wall images using previously performed CT scan as

the reference standard

Secondary outcome

NA

Study description

Background summary

The relevance of the proposed study lies in the optimization of a new 3 Tesla Magnetic Resonance Imaging protocol to visualize the aortic vessel wall

Study objective

optimization of a new 3 Tesla Magnetic Resonance Imaging protocol for imaging of the aortic vessel wall in order to enhance the identification of individuals at highest risk of developing clinically manifest atherosclerosis

Study design

cross-sectional study

Study burden and risks

We believe the benefits of the study will outweigh the risks and burden. The procedures performed are safe, without (long term) side effects and do no harm to the subject. The burden for the participants is little: only two times (at baseline and 4 weeks thereafter), participants will undergo an MR imaging

examination. The most important potential risk is the administration of contrast agent. However, the gadolinium chelate gadobutrol (Gadovist) belongs to the safest class of MRI contrast agent. In fact it is the standard contrast agent used for MRI examinations in the clinical setting. As such, it is administered to thousands of patients every year in our hospital. Not only is the frequency of side effects of Gadovist very low, if a side effect occurs, it is easy to treat, therefore health risks are minimal. In addition, if subjects are known to be allergic to contrast agents or have severe renal impairments, they are excluded from participation. Moreover, using MRI has several advantages: it is a safe procedure; does not use radiation and is suitable for repeated measurement without side effects; and is well-suited to assess various stages of atherosclerosis in a reproducible manner. Furthermore, MRI is able to distinguish between various components of atherosclerotic lesions (lipid core, thin caps, intra plaque hemorrhage) and atherosclerosis can already be assessed at a young age. The insights gained from this study may pave the way to enhance the identification of individuals at highest risk of developing clinically manifest atherosclerosis by using an appropriate, time-efficient MRI protocol.

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

- male or female
- volunteers
- 18 years or older
- Undergone cardiac triggered CT scan on which the aorta is visualized
- At least 1 plaque present in the aorta (defined as: luminal protrusion of > 1 mm in radial thickness);The maximum acceptable time interval between the performed CT-scanning and the MRI scan that will be performed for this study is at theis utmost 6 weeks.

Exclusion criteria

- pregnancy
- documented allergic reaction to gadolinium
- renal function below normal (GFR < 60ml/min)
- 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:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO Date:	01-10-2014
Application type:	First submission
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	NL49505.041.14