Visualizing gravity-dependent aortic endograft position with low-field MRI

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON20085

Source
Nationaal Trial Register

Brief title
GRAVEL

Health condition

Abdominal Aortic Aneurysm

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: University of Twente, Magnetic Detection & Imaging

Intervention

Outcome measures

Primary outcome

The aim of this explorative study is to evaluate existing geometrical parameters that are developed for supine imaging examinations (angles,
distances, surfaces, changes with respect to the spine) in upright scanning and to assess whether these parameters deteriorate from supine to

upright MRI scanning.

Secondary outcome

To evaluate if there is a correlation between the geometrical parameters obtained from the MR images with the measurements on CTA
examinations that are made in clinical practice.

Study description

Background summary

Endoleaks are leakages around endografts that occur after endovascular aortic aneurysm repair (EVAR). The origin of some endoleaks, which
cannot be detected by regular imaging like CTA, might be dependent on body position. This makes it impossible to find the leakage using CTA since
this is always performed in supine position. For this pilot study we focus on upright imaging of patients with an endoprosthesis and suspicion on the
endoleaks ‘type Ia’, with leakage at the proximal attachment site of the endograft, and ‘type V’, with no clear radiographic evidence for progression of the abdominal aortic aneurysm (AAA).

Low-field MRI offers the possibility for scanning in upright position. We want to visualize endograft geometry to measure endograft migration and
deformation. Implanted endografts have radiopaque (nitinol) markers present that are used for accurate endovascular placement, but these markers
can also indicate endograft geometry and position on MRI. An important clinical aspect of endoleaks that can be measured geometrically is the
'apposition' of the endograft, which is the distance covered by proximal endograft attachment to the aortic wall. The shorter this distance, the more
easily leakages on proximal attachment site occur. The challenging aspect is that not only the endograft but the complete aorta changes its geometry
after positional change. The goal of this project is to perform a pilot to validate whether we can accurately assess endograft position and geometry in
patients after EVAR.

The objective of this study is to see if the apposition and position of the endograft in the aorta changes between an upright and laying down position
of the patient. An upright position with other geometrical parameters than in supine position could cause position depended endoleaks. These kind of
endoleaks will be missed on regular CT-scans. So far, no studies have been performed with EVAR patients in upright (MRI or CTA) position. An
explorative study will be conducted using an open 0.25T MRI-system to assess endograft position with respect to relevant anatomical structures.

This explorative study will enlighten changes in endograft geometry and/or position in supine and upright position. The supine data will be compared
with regular CTA follow-up of these patients in which endograft geometry is measured in clinical practice. The final goal is to identify changes in
endograft geometry between a supine and upright position in patients after EVAR procedure. This possible change in geometry and/or position could
be a cause of an endoleak and thus growth of the AAA, indicating that endograft revision is necessary.

Our research question is whether low-field MRI would be suitable to detect changes in endograft geometry due to position and gravity accurately to
indicate possible causes of endoleaks after EVAR. Low-field MRI is the only suitable imaging modality to visualize these changes due to its ability to
image the patient in 3D both upright and supine.

Study objective

Low-field MRI is the only suitable imaging modality to visualize these changes due to its ability to image the patient in 3D both upright and supine.

Study design

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Contacts

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Eligibility criteria

Inclusion criteria

- Patient had previous EVAR intervention
- Implanted endograft: type Endurant or type Anaconda
- Patient had/will have CTA follow-up because of a suspected endoleak, or growth of the aneurysm
- Signed informed consent
- Good knowledge of Dutch language

Exclusion criteria

- Hip waist > 47 cm (because of MR coil restrictions)
- Not eligible for MRI, in response to the MRI safety checklist
- Inability to stand for 15 minutes, without assistance
- Outdated (>2 months) good contrast CTA scan
- Previous re-intervention to repair an endoleak after EVAR

Study design

Design

Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2019
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-10-2019

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48077
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8115
CCMO	NL69413.091.19
OMON	NL-OMON48077

Study results