Fattening of the Adventitia as MR Imaging basEd biomarker in AAA patients (FAME)

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To determine whether it is possible to identify adventitial fattening of the aortic wall in patients with an abdominal aortic aneurysm using MRI techniques and use this adventitial fattening as a new biomarker for AAA patients.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

Summary

ID

NL-OMON34591

Source
ToetsingOnline

Brief title
Fatty Adventitia Mri Evaluation (FAME)

Condition

- Aneurysms and artery dissections

Synonym
dilatation of the abdominal aorta., swelling of the aorta

Research involving
Human

Sponsors and support

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

Intervention

Keyword: abdominal aortic aneurysm, mr imaging, risk, rupture

Outcome measures

Primary outcome

adventitial fattening of the aortic wall.

Secondary outcome

The morphological description of the plaque, the number and size of the vaso vasora, the measurements of vascular wall stress, the pulse wave velocity measurements.

Aneurysm diameter, aneurysm related complaints, the serum markers of inflammation.

Age, length, height, gender, body weight, smoking, diabetes mellitus, cardiovascular risk pattern, family history of aneurysm presence, additional relevant medical history.

Study description

Background summary

We found that fat degeneration of the adventitial layer of the aortic wall is the main cause of rupture in AAAs. Therefore, the purpose of the present study is to evaluate adventitial fattening of the aortic wall in patients with an abdominal aortic aneurysm to provide a new tool for risk stratification in these patients.

Study objective

To determine whether it is possible to identify adventitial fattening of the aortic wall in patients with an abdominal aortic aneurysm using MRI techniques and use this adventitial fattening as a new biomarker for AAA patients.

Study design

First: Pilot study, Second: Pilot study and Third: a cross sectional study.

Study burden and risks

Currently the main criterion for abdominal aortic aneurysm (AAA) repair is an aneurysm diameter of >=5.5 cm. However, some AAA*s rupture when they are smaller, whereas other aneurysms are discovered when they have exceeded this critical diameter but have not ruptured. Amongst others, therefore it seems that size alone has a suboptimal sensitivity and specificity, causing costly unnecessary treatments or unexpected rupture. Therefore, a more sensitive and specific marker is wanted for the treatment of individual AAA patients.
Within this study the MRI scanner is used to determine if the adventitial fattening of the aneurysm wall can provide better risk stratification for these patients. The advantage of the MRI scanner is that it is believed to be harmless to the patient. The burden for the patients will be the gadolinium contrast during the MRI scan, the one vena punction, the time they spend filling out the questionnaire and the MRI scanning time. The questionnaire will be completed when the patients give their informed consent and the scanning & vena punction will take place the same day. There is no need for a second visit.

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

Volunteers: >= 18 years
Patients: >= 40 years, aneurysm patients (aneurysm is detected with ultrasound)

Exclusion criteria

A known gadolinium allergy, kidney dysfunction with a GFR <30 and patients with implants and (ferromagnetic) foreign bodies (pacemakers, vagus nerve stimulators, ICDs, loop recorders, insulin pumps, cochlear implants, deep brain stimulators, metal sliver in the eye, an intra-uterine device), claustrophobia , (possible) pregnancy before 12 weeks.

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:	95
Type:	Anticipated

Ethics review

Approved WMO Date:	30-05-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL33854.058.10