Advanced MRI in Abdominal Aortic Aneurysms

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1: Feasibility: to assess whether 4D flow MRI, DCE-MRI and T1/T2 mapping sequences can produce high-quality images that enable the calculation of the primary parameters wall shear stress (WSS), kinetic transport constant (Ktrans) and T1/T2…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

Summary

ID

NL-OMON47558

Source
ToetsingOnline

Brief title
Advanced MRI in AAA

Condition

- Aneurysms and artery dissections

Synonym
Abdominal aortic aneurysm; local enlargement of the main abdominal artery

Research involving
Human

Sponsors and support

Primary sponsor: Chirurgie
Source(s) of monetary or material Support: AMC Foundation

Intervention

Keyword: Abdominal aortic aneurysm, Feasibility, MRI, Reproducibility

Outcome measures

Primary outcome

4D flow MRI: wall shear stress (WSS);

DCE-MRI: wall permeability, expressed by the kinetic transport constant

(Ktrans);

T1/T2 mapping: T1/T2 relaxation time

Secondary outcome

4D flow:

- Peak flow velocity inside the aneurysm

- Location of peak wall shear stress

- Flow velocity at aneurysm entrance

- Descriptive flow patterns

- Oscillatory shear index

DCE-MRI:

- Quantitative reverse reflux rate constant kep

- Area under the curve of contrast uptake

- Peak enhancement ratio

- Wash-in slope

- Time to peak (TTP)

- Mean transit time (MTT)

T1/T2 mapping:

- No secondary parameters

Study description

Background summary

Abdominal aortic aneurysms (AAAs) are local dilatations of the abdominal aorta. They are generally asymptomatic, but can grow or eventually rupture. Rupture of an AAA is associated with high morbidity and mortality. Despite extensive research, the pathogenesis of aneurysm growth and rupture is not fully understood. Also, no clear rupture predictor has been identified to date.
Further research with imaging techniques can lead to a better understanding of the pathogenesis of AAA growth and rupture.
This MRI study uses four-dimensional flow Magnetic Resonance Imaging (4D flow MRI), Dynamic Contrast-Enhanced Magnetic Resonance Imaging (DCE-MRI) and T1/T2 mapping to visualise AAA characteristics.
4D flow MRI visualises blood flow. This enables the calculation of hemodynamic characteristics of AAA. DCE-MRI can visualise vessel wall microvasculature in the AAA wall. With T1/T2 mapping, the composition of intraluminal thrombus (ILT) can be measured.
These characteristics are thought to play a role in AAA rupture. Since these MRI sequences have only been explored in a handful of AAA studies, they will need to be tested for feasibility and reproducibility. It will also be tested whether the outcomes of these MRI sequences are associated with AAA diameter.

Study objective

1: Feasibility: to assess whether 4D flow MRI, DCE-MRI and T1/T2 mapping sequences can produce high-quality images that enable the calculation of the primary parameters wall shear stress (WSS), kinetic transport constant (Ktrans) and T1/T2 relaxation time;

2: Reproducibility: to assess the reproducibility of 4D flow MRI, DCE-MRI and T1/T2 mapping results in AAA by calculating interscan, intra- and interobserver variability;

3: Association with disease severity: to assess whether WSS, Ktrans and T1/T2 relaxation time each are associated with aneurysm diameter. We hypothesise that WSS is inversely associated with aneurysm diameter, and that Ktrans is positively associated with aneurysm diameter.

Study design

Multicentre cross-sectional cohort pilot study. This study comprises of two phases. In the first phase, 5 patients with an AAA undergo a single MRI examination to optimise the MRI sequences. In the second phase, a maximum of 30 patients with an AAA will be included to assess the three main objectives.

Study burden and risks

This is a non-invasive MRI study with the use of a contrast medium. All risks associated with this study are related to the use of the contrast medium. This study uses Gadovist as its contrast medium, which is registered for use in MRI research. Its complications are rare. Participation in this study may cause some discomfort to the patient due to the MRI scan time of approximately 45 minutes. The total MRI visit including all preparations will take approximately 2 hours.
Five patients will only be scanned once and a maximum of thirty patients will be scanned twice to assess reproducibility. The maximal number of visits is three per patient.
Lastly, participants will have no direct benefit from participation in this study.

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

- Adult patients (* 18 years of age)
- AAA with a maximal aneurysm diameter of at least 30 mm

Exclusion criteria

- Contra-indications for MRI
- Severely reduced renal function (eGFR <30)
- Previous allergic reaction to intravenous contrast agents
- Suprarenal AAA
- Pararenal AAA
- Previous aneurysm repair
- Inflammatory aneurysm
- Mycotic or other infectious aneurysm
- Vasculitis
- Connective tissue disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2017

Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT03138434
CCMO	NL56823.018.16