New MRI techniques for diagnosis and treatment of abdominal aortic aneurysms

Published: 09-02-2023
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The proposed pilot study will examine whether radiation-based CTA could be replaced with MRI in three phases of AAA management.

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

Summary

ID

NL-OMON53622

Source
ToetsingOnline

Brief title
MARVY

Condition

- Aneurysms and artery dissections

Synonym
abdominal aortic aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: TKI grant

Intervention

Keyword: AAA (abdominal aortic aneurysm), diagnostics, EVAR (endovascular aortic repair),

MRI (magnetic resonance imaging)

Outcome measures

Primary outcome

Phase 1: correlation between aneurysm growth (standard of care determinant for risk of AAA progression and rupture) and measured MRI parameters. Phase 2: difference between anatomical measurements (lengths and diameters) based on both CTA and MRA. Phase 3: difference in MRI parameters measured post-operatively in patients with and without EVAR related complications

Secondary outcome

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Study description

Background summary

Standard AAA management has several drawbacks. To start: maximum AAA diameter remains the central determinant in asymptomatic AAA management although it is not always reliable in identifying patients at risk of rupture. Secondly, EVAR outcome and occurrence of complications remain unpredictable due to poor prediction ability of CTA and US utilised in the follow-up protocol. Lastly, patients and physicians are being repeatedly exposed to cumulative radiation toxicity. All these drawbacks could be solved by trading the standard imaging modalities (CTA, US, DSA) by magnetic resonance imaging (MRI).

Study objective

The proposed pilot study will examine whether radiation-based CTA could be replaced with MRI in three phases of AAA management.

Study design

The proposed study is divided into two parts: part A and part B. Part A is a pilot study to optimise the DCE MRI sequence before we will use it in part B. Part B is an observational pilot study with participant inclusion in three

phases of the AAA management.

Study burden and risks

All risk associated with this study are related to the use of contrast agent. Dotarem is registered for use with MRI. 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.

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

Age > 18 years
Provision of written informed consent
For the patients --> Diagnosed with an abdominal aortic aneurysm

Exclusion criteria

Contra-indications for MRI:
Pregnant and/or breastfeeding women
Patients -->
Supra- or pararenal AAA,
Inflammatory, infectious or mycotic AAA
Ruptured AAA
Patients that underwent open surgical repair
Patients that are hypersensitive to contrast agent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-05-2023
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	PROUD patch
Registration:	No

Ethics review

Approved WMO Date:	09-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-12-2023
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
CCMO	NL80822.029.22