3D ultrasound of abdominal aortic aneurysm characteristics for predicting aneurysm shrinkage after endovascular repair

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

Summary

ID

NL-OMON51865

Source
ToetsingOnline

Brief title
3D US - EVAR

Condition

- Aneurysms and artery dissections

Synonym
abdominal aortic aneurysm, dilated large abdominal bloodvessel

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: Subsidie van Stichting Lijf en Leven

Intervention

Keyword: 3D ultrasound, abdominal aortic aneurysm, aneurysm characteristics, aneurysm shrinkage

Outcome measures

Primary outcome

The main study endpoint is the comparison between 3D non-CEUS, 3D CEUS and CTA

in measuring preoperative AAA characteristics, including AAA diameter, AAA

volume, lumen volume, thrombus thickness and thrombus volume.

Secondary outcome

Secondary study endpoints are:

- Feasibility of 3D CEUS of AAAs;

- Added value of contrast enhancement during 3D US;

- Category of AAA sac remodeling one-year after EVAR;

- Predictors of AAA sac remodeling one-year after EVAR.

Study description

Background summary

Abdominal aortic aneurysm (AAA) is a common vascular disease and can be treated with endovascular repair (EVAR). Aneurysm shrinkage one-year after EVAR has recently been shown to correlate to significantly better ten-year results after EVAR than patients without AAA shrinkage. Preoperative prediction of AAA shrinkage at one-year after EVAR could aid in patient selection and optimization of EVAR, resulting in an overall higher survival rate after EVAR. In literature, AAA thrombus, total AAA volume and lumen volume seem promising in predicting AAA sac remodeling after EVAR, although there is not enough evidence to draw firm conclusions yet. These AAA characteristics are traditionally measured with computed tomography angiography (CTA), however, three-dimensional ultrasound (3D US) is emerging as a novel imaging method for

AAAs. The PIUR 3D US system is based on electromagnetic tracking of two-dimensional ultrasound imaging, so each ultrasound image is captured in space and time. This results into a 3D reconstruction, and multi-planar reconstructions of the AAA. With the use of a US contrast agent, the AAA thrombus can also be separated from the flow lumen on the 3D scans. This way, 3D visualization of the AAA and its thrombus is enabled without the need for harmful radiation and nephrotoxic contrast agents, as opposed to CTA. In in vitro measurements, 3D US has already been shown to have clinically acceptable error rate with AAA diameter and volume measurement. However, it is unclear whether this is also applicable to in vivo measurements.

Study objective

The aim of this prospective one-year follow-up study is to investigate whether preoperative 3D US measurements of AAA characteristics with and without the use of a US contrast agent are comparable to CTA. The secondary objective is to identify potential 3D US predictors of AAA shrinkage one-year after EVAR and identify the added value of contrast enhancement for 3D US.

Study design

This is a prospective, explorative, cohort study.

Study burden and risks

In this prospective study, all surgical and medical procedures will be performed according to standard care. The study protocol will collect routine data. Efforts will be made to schedule the additional 30-40 minute 3D US measurement subsequent to a regular hospital appointment so that patients do not have to make an additional hospital visit for the study.The 3D US measurement includes the use of a widely used contrast agent, SonoVue, so an IV needs to be inserted. The scanning itself causes no additional discomfort as it is similar to regular US scanning. With these extra measurements we gain more knowledge of the added value of 3D US in AAA care. When confirming our hypotheses, we expect to introduce a novel, harmless imaging method to support clinical decision-making for AAA care. Furthermore, this study sets the first step towards AAA care without the need for CTA with its harmful radiation, toxic contrast agents, and higher costs.

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;
• Unruptured infrarenal or juxtarenal abdominal aortic aneurysm (AAA);
• Scheduled for elective endovascular repair (EVAR);
• Preoperative CTA with iodine contrast scheduled or already made;
• Informed consent form understood and signed.

Exclusion criteria

• BMI>40 kg/m2;
• Symptomatic AAA;
• Implanted pacemaker or ICD;
• Unable to hold breath for <=7 seconds;
• Pregnant;
• Hypersensitivity to the active substance(s) or any of the excipients in Sonovue;
• Known right-to-left cardiac shunt;
• Severe pulmonary hypertension (pulmonary artery pressure > 90mmHg);

• Uncontrolled systemic hypertension;
• Severe pulmonary disease (e.g. COPD GOLD 3 or 4, adult respiratory distress syndrome);
• Clinically unstable cardiac disease (recent, < 3 months, or ongoing myocardial infarction, unstable angina at rest, recent percutaneous coronary intervention, clinically worsening cardiac symptoms, severe cardiac arrhythmia*s, endocarditis, etc.);
• Prosthetic valves;
• Loss of renal function (GFR < 31 mL/min), end-stage renal disease;
• End-stage liver disease;
• Sepsis;
• Hypercoagulable status, recent (< 3 months) thrombosis;
• Congestive heart failure (class III or IV);
• Psychiatric or other condition that may interfere with the study;
• Participating in another clinical study that interferes on the primary outcomes of this study;
• 3D US measurement of AAA is impossible because of bowel gasses or other causes.

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):	02-01-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	3D ultrasound machine
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-08-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL81910.091.22