Feasibility of ultrasound particle image velocimetry to quantify flow in the abdominal aorta before and after endovascular aneurysm repair

Published: 21-07-2021
Last updated: 05-04-2024

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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-OMON52210

Source
ToetsingOnline

Brief title
EchoPIV in AAA trial

Condition

- Aneurysms and artery dissections

Synonym
Abdominal aortic aneurysm, enlargement of the large blood vessel

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: NWO TTW - VORTECS program,Bracco,Medtronic B.V.,Philips,Universiteit Twente

Intervention

Keyword: abdominal aortic aneurysm, contrast-enhanced ultrasound, hemodynamics, particle image velocimetry

Outcome measures

Primary outcome

Vector velocity data derived from the echoPIV analysis will be used to

calculate and visualize the spatiotemporal blood flow velocity profiles.

Secondary outcome

- Vector velocity data derived from the PC MRI scan will be used to calculate

and visualize the spatiotemporal blood flow velocity profiles and to validate

the echoPIV results.

- Pre- and postoperative spatiotemporal velocity profiles obtained with echoPIV

will be compared to evaluate the influence of the placement of a stent graft on

local hemodynamics.

- From both datasets blood flow derived parameters, such as vector complexity

and vorticity, will be calculated. Moreover, specific blood flow patterns like

recirculations or blood stasis will be evaluated thoroughly.

Study description

Background summary

An abdominal aortic aneurysm (AAA) is a common vascular disease with a high mortality in case of rupture. The underlying processes initiating aneurysmal degeneration and driving aneurysmal growth remain poorly understood. Local hemodynamics might play a key role in the pathogenesis of AAA, as it is

associated with aneurysmal growth, intraluminal thrombus formation and rupture risk. Visualizing and quantifying local blood flow profiles could eventually provide more insight in the underlying mechanisms of aneurysm progression as well as identify smaller AAA with increased vulnerability or larger AAA with low risk of rupture. Consequently, this may improve risk assessment and provide patient-specific therapy guidance. Nowadays, endovascular aneurysm repair (EVAR) is the preferred treatment modality in most patients with an infrarenal AAA. However, EVAR is associated with a relatively high reintervention rate. It is hypothesized that the placement of a stent graft may alter local hemodynamics and subsequent recirculations or flow stagnations promote the onset of thrombosis or micro-emboli. These unfavourable flow conditions might be related to various complications after EVAR, such as limb occlusion (6.5% within 6 months), renal dysfunction (3.3%), and the persistence of type II endoleaks (10.2% with type II endoleaks of which only 35.4% resolved spontaneously). Visualizing local blood flow profiles after EVAR might provide insight in these (un)favourable conditions.
In vivo blood flow quantification is a great challenge, particularly in the abdomen. Advanced ultrasound based techniques, incorporating ultrasound contrast agents and plane wave imaging, proved to be feasible in quantifying aortoiliac blood flow patterns in healthy volunteers.

Study objective

The aim of this study is to determine the feasibility of ultrafast contrast-enhanced ultrasound particle image velocimetry (echoPIV) measurements to quantify spatiotemporal blood flow velocity profiles in the abdominal aorta of AAA patients before and after endovascular repair.
Secondary objectives are to determine the correlation between echoPIV and phase-contrast MRI (PC MRI) based measurements to ultimately validate the spatiotemporal velocity profiles obtained with echoPIV. Furthermore, changes in blood flow velocity profiles after placement of a stent graft will be evaluated.

Study design

Feasibility study.

Study burden and risks

The burden for subjects related to this study consists of 1 extra visit to the hospital prior to their scheduled endovascular treatment. During this visit the preoperative echoPIV and PC MRI measurements will take place. The postoperative echoPIV measurements and PC MRI scan will not require an additional visit, since this will be scheduled on the same day as the clinical follow-up visit.
The echoPIV measurements will be performed using a research ultrasound machine that is not approved for clinical use. The required tests were performed to

ensure a safe use with the subjects. Moreover, during the echoPIV measurements an ultrasound contrast agent will be intravenously injected. With the use of these contrast agents there is a small risk of adverse events. To this end, appropriate safety measures have been realized at our vascular centre where the measurements will take place. Also, two PC MRI scans will be performed which is not part of standard care.

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

- Male or female > 18 years of age
- BMI * 30 kg/m2
- Infrarenal AAA
- Scheduled for elective EVAR

- Informed consent form understood and signed, and agrees to all visits

Exclusion criteria

- Hypersensitivity to the active substance(s) or any of the excipients in Sonovue
- 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)
- Pregnancy
- MRI exclusion criteria (pacemakers, cerebral vascular clips, claustrophobia)
- Heavily calcified aortoiliac arteries (based on the preoperative CT angiography scan)

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):	06-07-2022

Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	21-07-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-05-2022
Application type:	Amendment
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	NL77381.091.21

Study results

Date completed:	22-08-2023
Actual enrolment:	12