Feasibility of ultrasound particle image velocimetry to quantify swirling flow inside the flow-modulating Biomimics 3D vascular stent

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON51308

Source
ToetsingOnline

Brief title
EchoPIV to detect swirling flow

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral arterial disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: Ministerie van OC&W,Veryan Medical Ltd., London, UK

Intervention

Keyword: Biomimics 3D vascular stent, Contrast-enhanced ultrasound, Hemodynamics, Peripheral arterial disease

Outcome measures

Primary outcome

Vector velocity fields derived from echoPIV data will be used to calculate and visualize spatiotemporal blood flow velocity profiles. Offline analysis will be used to investigate the existence of swirling flow patterns.

Secondary outcome

Secundary study parameters are as follows:

- The spatiotemporal swirling blood flow patterns obtained with echoPIV with the patient in supine position and in sitting position will be compared to investigate the influence of the patients* position on swirling blood flow patterns.

- CTA images from the patients* upper leg will be used to assess the geometry of the treated vessel and its link to echoPIV outcomes in terms of swirling flow.

- Velocity estimates obtained with conventional Doppler ultrasound will be compared to echoPIV outcomes.

- Flow related parameters, indicating the presence of swirling flow, will be calculated.

Study description

Background summary

Peripheral arterial disease (PAD) of the lower extremity is the third leading cause of atherosclerotic cardiovascular morbidity. Endovascular revascularization has become the principal treatment strategy in most femoro-popliteal lesions. Veryan has developed a stent graft (BioMimics 3D stent) for the superficial femoral artery (SFA) that focuses on mimicking the native vessel geometry, which has a helical or non-planar shape. The helical shape could promote swirling flow, which in turn can creates high, protective, values of wall shear stress (WSS), increasing the treatment durability. The application of stents that promote helical anatomy is still novel and not yet common clinical practice. In-vitro studies with the BioMimics stent have been performed as well as clinical studies. However, fundamental in-vivo knowledge on the presence and most optimal shape of swirling flow induced by helical stents is lacking.

Study objective

The main objective of the current study is to determine the feasibility of spatial and temporal quantification of swirling blood flow inside the SFA of patients treated with the BioMimics 3D stent, using high framerate (HFR) contrast enhanced ultrasound (CEUS) and particle image velocimetry (PIV), in short echoPIV.

Secondary objectives are:
- To evaluate the influence of the position of the patient on the induced swirling flow patterns in the BioMimics 3D stent.
- To investigate the change in geometry of the patients* vessels after treatment with the BioMimics 3D stent based on CT angiography (CTA) scans.
- To compare the blood flow velocity outcomes obtained with echoPIV to outcomes of conventional Doppler measurements.
- To calculate flow derived parameters related to swirling flow.

Study design

Feasibility study.

Study burden and risks

The burden of this study consists of the possibility of 1 extra visit to the hospital. This visit includes the echoPIV measurements that are performed with a US machine that is not yet approved for clinical use. This machine has been thoroughly tested, used in various other clinical studies at Rijnstate, and is

judged to be safe for use in humans. Also, an approved ultrasound contrast agent (UCA) is injected through a venous cannula during the echoPIV measurements. There is a very small risk of adverse events associated with the use of this UCA. Appropriate safety measures have been taken to account for this. Finally, a CT angiography scan is performed that 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
- Stenotic lesion in the SFA treated with a BioMimic 3D stent
- Willingness to visit the hospital and undergo HFR-CEUS measurements and a CTA scan

- Signed informed consent

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 3/4, adult respiratory distress syndrome)
- Clinically unstable cardiac disease (recent or ongoing myorcardial infarction, unstable angina at rest, recent percutaneous coronary intervention (PCI), clinically worsening cardiac symptoms, severe cardiac arrythmia*s, endocarditis, etc.)
- Loss of renal function (GFR < 31 ml/min), end-stage renal disease
- Hypersensitivity to iodinated contrast media
- Hypercoagulable status, recent thrombosis
- Congestive heart failure (class III or IV)
- Pregnancy

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):	06-02-2023
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	BioMimics 3D
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-03-2022
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	NL80130.091.22

Study results

Date completed:	22-03-2023
Actual enrolment:	1