Flow quantification with ultrasound particle image velocimetry in patients with aortoiliac occlusive disease

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To identify local flow patterns that can predict disease progression and failure of stent patency in patients with untreated and treated atherosclerotic lesions in the aortoiliac tract.

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

Summary

ID

NL-OMON48975

Source
ToetsingOnline

Brief title
echoPIV in AIOD

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
peripheral arterial disease

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: stichting Lijf & Leven

Intervention

Keyword: aortoiliac occlusive disease, ultrasound particle image velocimetry, wall shear stress

Outcome measures

Primary outcome

The main predictor variables of this study are flow derived parameters, such

as: mean wall shear stress (WSS), oscillatory shear index (OSI), recirculation

and blood stasis. Clinical outcome parameters are: lesion severity (duplex US)

and ankle-brachial-index (ABI) in group A and primary stent patency in group B

and C.

Secondary outcome

not applicable

Study description

Background summary

Visualization of local blood flow patterns in the aortoiliac tract is challenging, but clinically relevant as specific flow perturbations could affect atherosclerotic disease progression and stent patency.

Study objective

To identify local flow patterns that can predict disease progression and failure of stent patency in patients with untreated and treated atherosclerotic lesions in the aortoiliac tract.

Study design

Prospective cohort study. Subjects will receive ultrasound particle image velocimetry (echoPIV) measurements at baseline to obtain blood flow velocity data and to calculate flow derived parameters. 2 year follow-up of subjects will be performed to measure clinical outcome parameters and the influence of the calculated flow parameters on these outcome parameters will be

investigated.

Study burden and risks

The burden of this study consists of several extra visits to the hospital during follow-up, including additional duplex ultrasound (US) examinations and ABI measurements that are not part of standard care (in group A). CT angiography scans are performed at baseline, that are not part of standard care in group A and for some patients in group B. There is a risk of unexpected findings due to this CTA scan.
For the echoPIV measurements at baseline, a research US machine is used that is not approved for clinical use. This machine was thoroughly tested and is judged to be safe for use in humans. Also, an 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.

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

Group A:
- Recently diagnosed untreated aortoiliac stenotic lesion, confirmed with Duplex US (>50%)
- Presence of claudication symptoms, but no pain at rest (Fontaine 2a / 2b)
- Exercise therapy prescribed,
Group B:
- Recent endovascular treatment of an iliac stenotic lesion through placement of a single stent. Group C:
- Recent endovascular treatment of extensive aortoiliac lesion with a CERAB or KS configuration.

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, clinically worsening cardiac symptoms, severe cardiac arrythmia*s, etc.)
- Loss of renal function (GFR < 45 ml/min)
- Congestive heart failure (class III or IV)
- Hypersensitivity to iodinated contrast media
- Age < 50 (group A)
- 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):	16-07-2018
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-01-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-11-2019
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	NL63077.091.17

Study results

Date completed: 16-02-2023

Actual enrolment: 120

Summary results
Trial is onging in other countries