Computational Fluid Dynamics for estimating the Pressure Gradient of Serial Stenotic Lesions

Published: 31-08-2021
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To determine the accuracy of computational fluid dynamic models for the quantification of the pressure gradient of tandem stenoses in the femoropopliteal artery, as compared to invasive pressure measurements.

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

Summary

ID

NL-OMON51232

Source
ToetsingOnline

Brief title
PreSet

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral arterial disease, vessel narrowing

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,St. Jude Medical

Intervention

Keyword: Computational Fluid Dynamics, Hemodynamic Severity, Stenosis

Outcome measures

Primary outcome

The main outcome parameter is the level of agreement between computational simulations and the measurements of the pressure gradient over the full lesion, as assessed by the limits of agreement by a Bland-Altman analysis.

Secondary outcome

Clinical improvement (improvement in Rutherford classification) after femoropopliteal angioplasty and an exploratory analysis of the predictive power for clinical response by the pressure gradient.

Study description

Background summary

Peripheral arterial disease (PAD) in the lower extremity is the third leading cause of atherosclerotic cardiovascular morbidity. For isolated stenotic lesions, the decision to treat can be based on well-documented and cost-effective anatomic and functional clinical modalities. For two or more stenotic lesions in proximity (tandem stenoses), no evidence-based, non-invasive treatment indication is available. Personalized patient models that rely on Computational Fluid Dynamics (CFD) have a proven track record as non-invasive treatment indication for coronary artery lesions and could aid treatment decisions for patients with tandem stenosis in the femoropopliteal artery.

Study objective

To determine the accuracy of computational fluid dynamic models for the quantification of the pressure gradient of tandem stenoses in the femoropopliteal artery, as compared to invasive pressure measurements.

Study design

Single-center, observational study with invasive measurements.

Study burden and risks

The study burden is minimal and is only related to the percutaneous angiography procedure for which the patients are planned on clinical grounds. During this procedure, the burden consists of an extension of the procedure by 15 minutes and minor radiation exposure. Patients possibly receive a benefit from the study procedure, as the pressure measurements provide additional information on the lesion severity for the treating physician. The study results contribute to a potentially optimized treatment for future patients with the same disease.

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
Written informed consent
Scheduled angiography and/or endovascular treatment for femoropopliteal stenotic disease
Two or more stenoses in the femoropopliteal artery
Pre-proccedural CT-angiography or MR-angiography of the femoropopliteal arteries

Exclusion criteria

Known atrial fibrillation with irregular ventricular response rate
Occluded superficial femoral artery or popliteal artery
Women of child-bearing age not on active birth control
Inability to sign informed consent

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):	08-03-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2021
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

ID: 25215
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77052.091.21
OMON	NL-OMON25215