

PreSet study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25215

Source

Nationaal Trial Register

Brief title

PreSet

Health condition

Peripheral Artery Disease

Sponsors and support

Primary sponsor: Rijnstate

Source(s) of monetary or material Support: Abbott Vascular

Intervention

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. The pressure gradient is measured during the endovascular procedure with a pressure wire, before angioplasty of the lesions.

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. The clinical improvement is measured at 2 months using the Rutherford classification after the endovascular intervention.

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. The study will assess 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 objective

The pressure gradient of tandem stenoses in the femoropopliteal artery computed by computational fluid dynamics has an intra-class correlation coefficient of 0.8 or higher

Study design

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Intervention

Pressurewire measurement after intra-arterial injection of a vasodilator

Contacts

Public

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Scientific

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Eligibility criteria

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-procedural 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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2021
Enrollment: 20
Type: Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion
Date: 09-04-2021
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51232
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9744
CCMO	NL77052.091.21
OMON	NL-OMON51232

Study results