The impact of optical coherence tomography on the decision-making process of endovascular treatment of femoropopliteal disease

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To investigate in a clinical study how often the use of intravascular optical coherence tomography for femoropopliteal stenotic lesions leads to alterations in treatment planning before and after stent placement, in comparison to traditional digital…

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

Summary

ID

NL-OMON52244

Source
ToetsingOnline

Brief title
Optimo study

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: Topkennis instituten high-tech systems and materials (TKI-HTSM),Abbott Vascular International BVBA

Intervention

Keyword: digital subtraction angiography, endovascular treatment planning, femoropopliteal disease, optical coherence tomography

Outcome measures

Primary outcome

The percentage of procedures in which OCT changed the DSA-based treatment

planning before and after stent placement to investigate the impact of OCT

imaging on treatment planning.

Secondary outcome

1. Patient-specific hemodynamics calculated by OCT-based CFD models and

CTA-based CFD models will be compared to investigate the added value of OCT in

the CFD models.

2. Areas with a low wall shear stress calculated by post procedural OCT- and

CTA-based CFD models will be compared to late luminal loss obtained from

patient follow-up to investigate which model performs best.

Study description

Background summary

Peripheral arterial disease is a severe clinical problem with an increasing prevalence due to an ageing population. Endovascular treatment, usually using stents, is recommended for the femoropopliteal tract. The patency of these stents is influenced by several factors, including stent sizing and stent positioning.
Current procedural planning of femoropopliteal disease is primarily based on

single-plane digital subtration angiographies (DSA). This modality provides a 2D image of the vessel lumen, which may be suboptimal for stent sizing and it may be difficult to choose the optimal stent position as minor lesions may be missed. Suboptimal treatment could result in unfavourable levels of wall shear stress causing the vessel wall to be more susceptible to neo-intimal hyperplasia ultimately causing restenosis and stent failure. Intravascular optical coherence tomography (OCT) is able to visualize the arterial wall with a micrometer resolution, which could result in better stent sizing. Furthermore, OCT is able to visualize different layers in the vessel wall and identify unhealthy areas, which may lead to a more optimal stent placement as unhealthy areas can be covered completely. Moreover, OCT provides detailed patient-specific geometries necessary to develop reliable computational fluid dynamics (CFD) models that simulate blood flow in stented arteries and calculate wall shear stresses, which could predict stent patency.

Study objective

To investigate in a clinical study how often the use of intravascular optical coherence tomography for femoropopliteal stenotic lesions leads to alterations in treatment planning before and after stent placement, in comparison to traditional digital subtration angiography based treatment planning.

Study design

Exploratory observational study.

Study burden and risks

The burden of this study consists of two OCT measurements during intervention and a computed tomography angiography scan during follow-up, which are both not part of standard clinical care. OCT is standard-of-care in the coronary arteries and was found to be safe in the superficial femoral artery. In select cases minor and temporary patient discomfort during saline injection for the OCT measurement was reported.

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

Aged 18 years or older
Written informed consent
Scheduled endovascular treatment of femoropopliteal stenotic lesions with a Supera or Absolute stent
Clinically and hemodynamically stable

Exclusion criteria

Occluded superficial femoral artery or popliteal artery
Superficial femoral artery and/or popliteal artery diameter larger than 6.5 mm
Severely impaired renal function (eGFR < 30 ml/min), end stage renal disease
Cardiac insufficiency (NYHA 3-4)
Hypersensitivity to iodinated contrast media
BMI > 25 and contralateral approach not possible
Minimal lumen diameter of target lesion < 1.5 mm
Presence of a hemodynamically significant inflow stenosis in the aorto-iliac tract or the common femoral artery
Participating in another trial with an investigational drug or medical device concerning the femoropopliteal tract, interfering with the current study
Life expectancy of less than 24 months
Woman of child-bearing age not on active birth control

Legally incapable

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):	02-03-2022
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	01-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-01-2023
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
ClinicalTrials.gov	NCT05057637
CCMO	NL75458.091.20