In-vivo validation of non-invasive, magnetic resonance or computed tomography based patient-specific pressure model to determine the severity of common and external iliac artery obstructions, and the need for revascularization non-invasively.

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The primary objective is validation of the MRA or CTA based personalized pre-procedural computer model, with intra-arterial pressure measurements at rest and during pharmacologically induced hyperemia, which serves as the gold standard.

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

Summary

ID

NL-OMON49149

Source
ToetsingOnline

Brief title
DETECT-PAD study 2.0

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Intermittent claudication, peripheral arterial disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: De kosten van de extra functie onderzoeken en beeldvorming worden betaald door de "Dutch Endovascular Alliance" (KvK 51310341 IBAN: NL28ABNA0451884256) respectievelijk; Tevens is er een bijdrage geleverd van 80.000 euro door het St. Antonius Onderzoeksfonds

Intervention

Keyword: Diagnoses optimization, Non-invasive modelling, Patient-specific modelling, Peripheral arterial disease

Outcome measures

Primary outcome

Not applicable. In vivo measured data is compared with data predicted by a

mathematical model.

Secondary outcome

Not applicable.

Study description

Background summary

The current study is a follow-up study of the DETECT-PAD study registered at www.toetsingonline.nl under number NL 45019.100.13. The DETECT-PAD study was a pilot study with the objective to quantify the hemodynamic significance of borderline iliac artery stenosis based on an invasive imaging technique. The developed computer model was validated by comparing the predicted pressure gradient with the measured intra-arterial pressure gradient. Also, the influence of the input parameters on the predicted pressure gradient was investigated. It was concluded that geometrical and functional (flow) parameters were the most important for an accurate estimation of the pressure gradient. The model yielded a total predictive value of 88% for distinguishing non-hemodynamically significant stenosis (*p<10 mmHg) from hemodynamically significant stenosis (*p*10 mmHg) as compared to the intra-arterial pressure

measurements (gold standard) [13]. However, the model was only tested using per-procedural data, i.e. rotational angiography (3DRA). Patients with non-significant iliac artery stenosis (*p<10 mmHg) were unnecessary exposed to iodinated contrast and radiation (20% of the included patients). Ideally, the pressure gradient would already be known before the interventional procedure.
In the DETECT-PAD study 2.0 the computer model will be validated using pre-procedural data. As geometrical input is very important, it is imperative to have sufficient resolution i.e. the Magnetic Resonance Angiography and Computed Tomography Angiography images should have similar high resolution as the 3DRA images used in the prior study. The computer model designed and validated in the earlier DETECT-PAD study will be used in this study. Therefore, large parts of this study protocol overlap with the protocol of the earlier conducted DETECT-PAD study.

Study objective

The primary objective is validation of the MRA or CTA based personalized pre-procedural computer model, with intra-arterial pressure measurements at rest and during pharmacologically induced hyperemia, which serves as the gold standard.

Study design

Prospective, observational, multi-center study

Study burden and risks

Patients are treated according to the standard of care. The model prediction does not have any influence on the treatment of the patient. All devices, guidewires and catheters used in this study have CE-approval (1434-MDD-32/2011). Participating patients will undergo a treadmill-test, ankle-brachial index measurement, duplex ultrasound and a CE-MRA or CTA which is standard of care. In case the subject undergoes CE-MRA additional MR-flow measurements will be performed. This prolongs the standard CE-MRA with 15 minutes. No additional contrast agent is needed and therefore there is no additional risk. In case the study subject undergoes a pre-procedural CTA, blood velocity will be subtracted from the duplex ultrasound measurement (which is standard of care). Next, the patients will undergo endovascular treatment which starts with the acquisition of a rotational angiography (3DRA). The additional radiation burden as compared to the standard digital subtraction angiographies is estimated to be <2 mSv, and considered a minimal risk to the patient*s health. The remainder of the endovascular therapy consists of all standard of care procedural steps. However, prior to treatment intra-arterial blood pressure measurements will be performed. To perform these measurements the pressure monitoring guidewire and fluid filled diagnostic catheter are

positioned proximally and distally from to the lesion, respectively. Measurements will be performed according to the instructions for use [6 10]. These additional measurements will prolong the intervention with a maximum of 15 minutes and take <5 minutes of extra fluoroscopy time. Intra-arterial pressure measurements already became an intrinsic part of modern interventional cardiology [17 18]. No follow-up or extended hospital stay is needed in this study.

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 over 18;
Symptomatic, chronic atherosclerotic lesions of the common or external iliac artery;

One or multiple borderline (50-70%) stenosis measured with ultrasound;
Rutherford class 1-6;
Signed informed consent.

Exclusion criteria

Inability to undergo all measurements;
Mental disability that hinders the ability to understand and comply with the informed consent;
Pregnancy or breast-feeding;
Renal insufficiency (e-GFR<30 ml/min/1.73m2);
Patients with acute ischemic limbs or aneurismal iliac lesions;
Patients with intimal dissections;
Patients with occlusive inflow (aortic) and/ or occlusions of the target iliac arteries.

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):	24-08-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2017
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL59300.100.16
Other	Trial NL6301