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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	-

Summary

ID

NL-OMON22159

Source
NTR

Brief title
DETECT-PAD study

Health condition

Peripheral Arterial Disease (PAD)
Perifeer arterieel vaatlijden (PAV)

Sponsors and support

Primary sponsor: St. Antonius Hospital
Source(s) of monetary or material Support: Volcano Corporation
Dutch Endovascular Alliance (DEALL)

Intervention

Outcome measures

Primary outcome

Validation of the personalized pressure model with intra-arterial pressure and flow measurements (model validation), and intravascular ultrasound (model input validation) that serves as the gold standard.

Secondary outcome

Validation of the by the model predicted increase of blood pressure after successful intervention of the stenosis

Comparing the diameter estimated by conventional pre-procedural measurements techniques {i.e. visual inspection (”eye-balling”), Contrast Enhanced Magnetic Resonance Angiography (CE-MRA), High Spatial Resolution Magnetic Resonance Imaging (HR-MRI), standard angiography and angiography images analyzed by 3 dimensional Quantitative Vascular Analysis (QVA 3D) software (Pie Medical Imaging, Maastricht, The Netherlands) } with the gold standard (IVUS).

Study description

Study objective

The one-dimensional personalized pressure model is able to predict the pressure drop over stenotic lessions in the common and external iliac arteries.

Study design

N.A.

Intervention

Standard of care percutaneous transluminal angioplasty (PTA) procedures with additional intravascular ultrasound (IVUS) and in-vivo pressure gradient measurements performed in one of the common and external iliac arteries.

Contacts

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Eligibility criteria

Inclusion criteria

(1) Age over 18;

(2) Symptomatic, chronic atherosclerotic lesions of the common iliac artery or external iliac artery;

(3) Single or multiple borderline (50-70%) stenosis measured with ultrasound;

(4) Rutherfordclass 1-6;

(5) Signed informed consent.

Exclusion criteria

(1) Previous endovascular or surgical treatment of the target iliac arteries;

(2) Inability to undergo all measurements (e.g. usual MRI contra-indications);

(3) Mental disability that hinders the ability to understand and comply with the informed consent;

(4) Pregnancy or breast-feeding;

(5) Renal insufficiency (e-GFR<30 ml/min/1.73m2);

(6) Known allergy to gadolinium based contrast agents;

(7) Patients with acute ischemic limbs or aneurismal iliac lesions;

(8) Patients with occlusive inflow (aortic) and/ or outflow (common femoral artery) disease.

Study design

Design

Intervention model: Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2014
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	09-03-2015
Application type:	First submission

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
NTR-new	NL4813
NTR-old	NTR5085
Other	NL45019.100.13 : Toetsingonline

Study results