Perfusion Angiography and Critical Limb Ischemia.

No registrations found.

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

Summary

ID

NL-OMON23986

Source
NTR

Brief title
PALI

Health condition

Critical Limb Ischemia (CLI)

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam.
Source(s) of monetary or material Support: Philips Medical Systems Nederland B.V.

Intervention

Outcome measures

Primary outcome

To study the role of pre- and post- angioplasty perfusion data in patients with critical limb ischemia in relation to clinical outcome at 12 months.

Secondary outcome

Correlation between perfusion angiography and non-invasive measurements, differences in perfusion between diabetic and non-diabetic patients.

Study description

Background summary

This evaluation investigates the prognostic value of perfusion angiography software to be used during CLI interventions. Quantitative analysis of the software data will determine how well the software predicts the clinical outcome of CLI patients. Also, patient demographics and non-invasive measurements (standard of care treatment) will be collected in this study.

Study objective

Perfusion Angiography, in relation with known parameters, describes the ultimate prognostic model in revascularized Critical Limb Ischemia patients.

Study design

The total duration of the study is expected to take approximately 2 years.

Intervention

The patient will undergo standard of care medical treatment for his or her CLI condition. During the procedure, the interventionalist will take runoffs of the affected leg and foot, before and after the revascularization procedure. The DSA of the foot, pre- and post, will be automatically processed in the perfusion angiography software solution and displayed on the workstation in the control room. Retrospectively, the data will be post-processed and quantitative analysis will take place. After the procedure is finished, the patient will go home. When the patient returns to the outpatient clinic (standard of care), healing of the wound will be logged.

Contacts

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Eligibility criteria

Inclusion criteria

1. Critical limb ischemia according to consensus document with a non-healing ulcer or gangrene.

2. Duration of complaints > 2 weeks.

3. Scheduled for DSA with endovascular intervention below the knee.

Exclusion criteria

1. Critical limb ischemia due to acute arterial occlusion.

2. No options for infra-popliteal angioplasty.

3. Allergy to contrast.

4. inability to give informed consent.

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2015
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-07-2015
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	NL5190
NTR-old	NTR5338
Other	METC van het AMC : W15_144# 15.0172

Study results

Summary results
It is the intention of the investigator and sponsor to submit the clinical study data for publication.