Perfusion Angiography and Critical Limb Ischemia.

Gepubliceerd: 30-07-2015 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23986

Bron
NTR

Verkorte titel
PALI

Aandoening

Critical Limb Ischemia (CLI)

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam.
Overige ondersteuning: Philips Medical Systems Nederland B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2015
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-07-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5190
NTR-old	NTR5338
Ander register	METC van het AMC : W15_144# 15.0172

Resultaten

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