The value of Perfusion Angiography in Critical Limb Ischemia

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The first objective is to determine the reproducibility and reliability of Perfusion Angiography. The second is to investigate the predictive value of Perfusion Angiography for wound healing in Critical Limb Ischemia.

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

Samenvatting

ID

NL-OMON25243

Bron
NTR

Verkorte titel
REPEAT

Aandoening

Critical Limb Ischemia

Ondersteuning

Primaire sponsor: St Antonius Hospital, Nieuwegein, The Netherlands
Overige ondersteuning: Philips Medical Systems Nederland BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A) Reproducibility and inter-rater reliability Perfusion Angiography
B) correlation between Perfusion Angiography and wound healing at 3 months in comparison

to traditional DSA

Toelichting onderzoek

Achtergrond van het onderzoek

Predicting the success rate of wound healing in CLI is difficult. Currently applied methods do not correlate well with the clinical situation and are not applicable during revascularization procedures.

This study investigates the reproducibility and reliability of Perfusion Angiography and the prognostic value in predicting wound healing.

Doel van het onderzoek

The first objective is to determine the reproducibility and reliability of Perfusion Angiography. The second is to investigate the predictive value of Perfusion Angiography for wound healing in Critical Limb Ischemia.

Onderzoeksopzet

The total duration of the study is expected to be 24 months.

Onderzoeksproduct en/of interventie

Perfusion Angiography will be performed during revascularization procedures. Extra runs will be performed to investigate reproducibility and the correlation with wound healing. Perfusion Angiography results will be reviewed in retrospect so that the revascularization procedures are not influenced by the results.

Contactpersonen

Publiek

Daniel A.F. van den Heuvel,
Koekoekslaan 1

Nieuwegein 3430 EM
The Netherlands
0031 88 320 3000

Wetenschappelijk

Daniel A.F. van den Heuvel,
Koekoekslaan 1

Nieuwegein 3430 EM
The Netherlands
0031 88 320 3000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosed with CLI according to the TASC II Working Group criteria

2. Present with non-healing ulcers or gangrene (RB 5-6)

3. Older than 18 years

4. No or adequately treated inflow disease

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Severe renal failure defined as an eGFR <30 mL/1.73 m2

2. Severe allergy to contrast medium with an absolute contra-indication

3. Pregnancy

4. Scheduled or anticipated major amputation (above the ankle)

5. Inability to position the foot in the footrest used for Perfusion Angiography

6. Inability to give informed consent

7. Distal embolization after treatment of inflow vessels

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2017
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-08-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43228
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6273
NTR-old	NTR6615
CCMO	NL59437.100.16
OMON	NL-OMON43228

Resultaten

Samenvatting resultaten
Data will be published in peer reviewed journal(s)