

Introducing Laser Speckle contrast imaging in the hybrid operating theatre in patients with PAOD

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The primary objective is to analyse whether Laser Speckle Contrast Imaging (LSCI) could be integrated in an endovascular operation program in a Hybrid Operating Theatre (HOT), for the visualisation of the microcirculation of the foot in patients...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23881

Bron

NTR

Aandoening

peripheral arterial occlusive disease

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente

Overige ondersteuning: University of Twente

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to analyse whether LSCI could be integrated in a PAOD endovascular operation program in a HOT, for the visualisation of the foot microcirculation.
 If LSCI could be integrated, the primary objective will be extended to determine a correlation

between LSCI outcome values and clinical outcome after an endovascular procedure in patients with PAOD.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction: In peripheral arterial occlusive disease (PAOD) one or more arterial stenosis, cause a change in haemodynamics. The change in haemodynamics results in an insufficient blood supply in the legs. In end stadium PAOD this can result in severe claudication or tissue loss. Worldwide, 200 million patients are suffering from PAOD. To prevent tissue loss or to resolve severe claudication, PAOD patients are treated endovascularly by means of Percutaneous Transluminal Angioplasty (PTA), possibly supplemented with the placement of a stent. In Medisch Spectrum Twente (MST) Enschede these endovascular procedures, are carried out, since January 2016, in the Hybrid Operating Theatre (HOT). Visualization of blood and oxygen delivery to the affected tissue, the microcirculation in the patients foot, is not yet possible with the current imaging techniques used in the HOT. Therefore, besides the conventional fluoroscopy and angiography, a second imaging module should be present in the PAOD endovascular operation program, that can visualise the microcirculation of the foot, throughout the entire PTA procedure. This second imaging module will show a peroperative outcome/effect of the endovascular treatment to the affected tissue, which is not yet possible. Laser Speckle Contrast Imaging (LSCI) could be the solution to provide this method of imaging to have a visualisation of the procedure outcome peroperative. The clinical impact of the addition of LSCI, is a better peroperative feedback about blood flow in the target area, the foot microcirculation.

Rationale: The rationale of this research is to determine whether LSCI could be integrated in a PAOD endovascular operation program in a HOT, for the visualisation of the microcirculation of the foot. Therefore, stability and reproducibility of the system, environmental factors and the influence of general anaesthesia on the measurement outcome needs to be investigated.. If LSCI shows high stability and reproducibility, the outcome parameters of the techniques need to be correlated to the clinical outcome after the endovascular procedure.

Objective: The primary objective is to analyse whether LSCI could be integrated in a PAOD endovascular operation program in a HOT, for the visualisation of the microcirculation of the foot. When LSCI can be integrated, the rationale of this research is expanded to determine a correlation between LSCI outcome values and clinical outcome after an endovascular procedure in patients with PAOD.

Study design: Prospective exploratory observational single centre (MST Enschede) pilot study, followed by a prospective observational single centre (MST Enschede) cohort study.

Study population: Patients (n=30 for pilot study) with PAOD, aged 18 years or older, will be imaged with LSCI.

Main study parameters/endpoints: The main study parameters will be perfusion images and graphs of the foot microcirculation of patients with PAOD, measured with LSCI.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There are no direct benefits for the subject on short term. The subjects do contribute to more knowledge about the treatment of PAOD, so that in the future, patients with PAOD can be better treated. The used technique, LSCI, is safe for the patient when applied. For the patient there are no risks associated with LSCI.

Doel van het onderzoek

The primary objective is to analyse whether Laser Speckle Contrast Imaging (LSCI) could be integrated in an endovascular operation program in a Hybrid Operating Theatre (HOT), for the visualisation of the microcirculation of the foot in patients with peripheral arterial occlusive disease (PAOD).

When LSCI can be integrated, the rationale of this research is expanded to determine a correlation between LSCI outcome values and the clinical outcome after an endovascular procedure in patients with PAOD

Onderzoeksopzet

Multiple measurements during one endovascular procedure.
Measurements will take as long as the operation time.

Onderzoeksproduct en/of interventie

Two LSCI measurements will be made before general anaesthesia.

Two LSCI measurements will be made directly after applying general anaesthesia.

Continuous LSCI measurements are performed during the entire endovascular procedure.

Before ending general anaesthesia, two last LSCI measurements will be performed.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients with end stage PAOD (Rutherford CLI grade 4-5-6)
- First/initial intervention for PAOD
- Procedures performed in the HOT, MST Enschede
- Procedures performed under general anaesthesia
- Aged 18 years or more

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- Re-interventions for PAOD
- Amputation (partial) of foot or toes in medical history
- Local anaesthesia
- Multiple drug resistance (MDR) (Dutch: BRMO)
- Tattoo at the plantar side of the foot

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2018
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45778

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7241
NTR-old	NTR7440
CCMO	NL66041.044.18
OMON	NL-OMON45778

Resultaten

Samenvatting resultaten

Not applicable