Assessing of the microcirculation of the foot, using Laser Speckle Contrast Imaging in patients with end stage PAOD undergoing revascularisation in the Hybrid Operating Theatre

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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. Therefore, stability and reproducibility of the system,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON45778

Source
ToetsingOnline

Brief title
Assessing of the microcirculation of the foot, using LSCI

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
etalagebenen, Peripheral Arterial Occlusive Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hybrid Operating Theatre, Laser Speckle Contrast Imaging, Microcirculation, peripheral Occlusive Arterial disease

Outcome measures

Primary outcome

The main study parameters will be perfusion images and graphs of the foot

microcirculation of patients with PAOD, measured with LSCI. Stability and

reproducibility of the LSCI technique will be analysed.

Secondary outcome

- Analyse if there is a drift/arise of a system error, in the measurements

during long measurements (>1 hour)

-Environmental induced

-System induced

Study description

Background summary

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.

Study objective

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. Therefore, stability and reproducibility of the system, environmental factors and the influence of general anaesthesia on the measurement outcome needs to be investigated.

Study design

Single centre (MST Enschede) blinded observational pilot study, followed by a prospective observational single centre (MST Enschede) cohort study.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	PeriCam PSI
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-01-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Not approved

Date:	08-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23881
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66041.044.18
OMON	NL-OMON23881