Pilot study of non-invasive tissue perfusion imaging in Peripheral Arterial Disease with MultiSpectral Optoacoustic Tomography

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

Summary

ID

NL-OMON49494

Source
ToetsingOnline

Brief title
Stupendous

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral arterial disease - Constricted bloodflow to the legs

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Lijf en Leven

Intervention

Keyword: MSOT imaging, Peripheral arterial disease, Tissue Perfusion

Outcome measures

Primary outcome

The main endpoint is the visualization and quantification of oxygenated and deoxygenated haemoglobin, in healthy volunteers, claudicants and patients with limb-threatening limb ischemia.

Secondary outcome

The second endpoint is a standardized measurement protocol for MSOT imaging in the lower extremity in order to optimize precision and accuracy of the measurements. A endpoint is the change in optocoustic signal before, during and after cuff occlusion.Other endpoints are MSOT signal intensity in reference to standard diagnostics such as, ABI, TBP, Doppler wave forms, severity of stenosis on CTA (or MRA), and TcPO2 measurements. Another endpoint is the visualization of the affected arteries and measured difference in oxygenated and deoxygenated haemoglobin before and after treatment in claudicants and patients with critical limb-threatening ischemia.

Study description

Background summary

Peripheral arterial disease (PAD) of the limbs is a progressive and common disease. Symptoms of PAD include pain, and when the disease progresses to critical limb-threatening ischemia, resting pain and non-healing ulcers. The symptoms are the result of impaired tissue perfusion. To determine the severity

of PAD, but even more important to localize ischemic regions in the lower extremity, tissue perfusion imaging may be extremely relevant. Today, the most common studied modality for non-invasive tissue perfusion measurements is transcutaneous partial pressure of oxygen (TcPO2). Unfortunately this technique has some limitations. It is operator dependent, time consuming and not well suited for everyday clinical use. A potentially more appropriate technique is Multi-Spectral Optoacoustic Tomography (MSOT). It is a new non-invasive imaging technique with real-time visualization of the ratio of oxygenated and deoxygenated haemoglobin, and therefore tissue oxygen saturation. As such, anatomical and perfusion characteristics of blood vessels can be combined. Therefore, this imaging modality has the potential to evaluate the effects of treatments in patients with PAD quantitatively and accurately.

Study objective

This study aims to investigate the feasibility and clinical performance of tissue perfusion imaging with MSOT in the lower extremity of healthy volunteers, claudicants and patients with critical limb-threatening ischemia. The main objective is to optimize MSOT to quantify tissue saturation by resolving oxygenated and deoxygenated haemoglobin in these three categories of subjects. The second objective is to develop a standardized measurement protocol for the MSOT imaging in the lower extremity to optimize precision and accuracy of the measurements.Another objective is to determine changes in tissue saturation after hyperemia test due to cuff occlusion of the upper leg in healthy volunteers. Other objectives are to evaluate tissue saturation determined with MSOT in reference to standard diagnostics such as ankle/brachial index (ABI), toe systolic blood pressure (TBP), Doppler ultrasound and TcPO2 measurements. The final objective is to visualize the affected arteries and to determine tissue perfusion values before and after supervised exercise in claudicants or revascularization procedures in patients with critical limb-threatening ischemia.

Study design

This study is a single center pilot study to investigate the feasibility and clinical performance of MSOT imaging in 10 healthy volunteers, 10 claudicants (Rutherford 2-3) and 10 patients with critical limb-threatening ischemia (Rutherford 4-6). In all participants MSOT imaging will be performed on the calf muscle and the plantar side of the foot. Additionally a TcPO2 measurement will be performed on the calf muscle. Healthy volunteers will undergo cuff occlusion of the upper leg to induce a hyperemia test during MSOT imaging. Claudicants will be imaged before and after supervised exercise in combinations with TcPO2 measurements. Patients with critical limb-threatening ischemia will receive MSOT imaging before and after revascularization procedures in combination with TcPO2 measurements. The post-procedure measurements will be performed before discharge from the hospital and after 6 weeks in combination

with the regular appointmet at the outpatient clinic. In all patients, the anterior tibial artery and dorsal pedal artery will be imaged before and after treatment next to the calf muscle and the foot. The measurements are additional to standard diagnostics such as, ABI, TBP, Doppler ultrasound and CTA, for both patient groups. The study measurements will not influence diagnostics and treatment of the patients, and all patients will receive diagnostics and treatment according to standard of care.

Study burden and risks

The risks associated with participation with this study are low. The MSOT system is an investigational device that has been developed by iThera Medical GmbH in collaboration with the UMCG. The device uses a class IV laser, which has some potential risk of causing damage to the eye when exposed to the laser light directly. Special safety measurements, like an interlock system, warning lights, laser safety training and laser safety goggles with corresponding SOPs are all taken to minimize risks for the patient and caregiver. Healthy volunteers will only receive MSOT imaging and TcPO2 measurements once. For claudicants and patients with critical limb-threatening ischemia no additional hospital visits are required. MSOT imaging will be scheduled together with regular appointments and will take about 60 minutes. For both of these patient groups regular outpatients visits, hospital visits, diagnostics and treatment are according to standard of care, and not affected by the study. Therefore, the burden of participation is low. The study results will not affect diagnostics or treatment of the patients. There are no direct benefits for patients concerning the treatment they are receiving.

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

Healthy volunteers:
- 18 years and older
- Written informed consent
- Rutherford classification 0
Patients with PAD:
- 18 years and older
- Written informed consent
- Claudicants, Rutherford classification 2 and 3.
- Critical limb ischemia, Rutherford classification 4 to 6.

Exclusion criteria

Healthy volunteers:
- Investigations or treatment for peripheral vascular disease
- Symptoms or history of peripheral neuropathy
For both healthy volunteers and patients with PAD:
- Insufficient knowledge of the Dutch language, illiteracy or language barrier.
- Concurrent uncontrolled medical conditions
- Lower leg fractures within the past 12 months
- Severe peripheral pitting oedema.
- Severe cardiac-pulmonary failure.
- Active cellulitis-erysipelas of the legs or other dermatological diseases.
- (Partial) amputation of one of the feet and/or legs.
- Pregnancy or lactation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2022
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-07-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL70662.042.19
Other	NL8091