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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24597

Source
Nationaal Trial Register

Brief title
Stupendous study

Health condition

Peripheral arterial disease. Diabetes mellitus. Ulceration

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: UMCG

Intervention

Outcome measures

Primary outcome

The main objective is to quantify tissue saturation by resolving oxygenated and

deoxygenated haemoglobin in healthy volunteers, claudicants and patients with critical limb threatening ischemia.

Secondary outcome

 To develop a standardized and optimized measurement protocol for MSOT imaging in the lower extremity, including most adequate location on the lower leg in order to optimize precision and accuracy of measurements.
 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.
 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 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. 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. 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 objective

We hypothesize that MSOT imaging can determine tissue perfusion in the lower extrimity of healthy volunteers and patients with PAD, and therefore detect disease, disease progression and can detect changes in tissue perfusion following treatment for PAD.

Study design

Before and after treatement

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

For this study 30 subjects will be included: 10 healthy volunteers, 10 claudicants or patients with non-critical limb ischemia (Rutherford 2-3) and 10 patients with critical limb-threatening ischemia (Rutherford 4-6). All subjects have to be older than 18 years.

Exclusion criteria

Healthy volunteers:
- Symptoms or history of 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8091
Other	METc UMCG : 201900420

Study results