# Non-invasive imaging of Peripheral Vascular Disease with MultiSpectral Optoacoustic Tomography (PVD-MSOT).

No registrations found.

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

## Summary

### ID

NL-OMON20951

**Source**
NTR

**Brief title**
PVD-MSOT

**Health condition**

Peripheral vascular disease, MSOT, atherosclerosis, diabetes mellitus, Fontaine classification, duplex ultrasound

Perifeer vaatlijden, atherosclerose, Fontaine classificatie, echo duplex.

### Sponsors and support

**Primary sponsor:** University Medical Center Groningen (UMCG).
http://www.umcg.nl
**Source(s) of monetary or material Support:** University Medical Center Groningen (UMCG).

### Intervention

### Outcome measures

### Primary outcome

The study aims to acquire MSOT images at landmarks of both feet of each included patient. These landmarks correspond to either large arteries (e.g. arteria tibialis posterior) or regions where microvasculature should be assessed (e.g. pads of each toe). The acquired images will then be analyzed to obtain the following parameters:

Microvascular parameters
- Quantification of total amount of HbO2 per volume at landmarks

Large artery parameters
- Hemoglobin oxygen saturation
- Morphology (normal/plaque)

### Secondary outcome

To investigate whether pathological changes can be seen in the MSOT images which correlate with findings in standard diagnostics (e.g. Fontaine classification, ABI, duplex ultrasound) and additional measurements, comprising Advanced Glycation Endproducts (i.e. skin autofluorescence¡ªAGE reader device) and pulse oximetry of the toes.

## Study description

### Background summary

This study aims to investigate the feasibility and clinical performance of MSOT imaging of the feet in Peripheral Vascular (PVD) patients. Our main objective is to investigate and obtain new information about the state of arteries in PVD patients using MSOT. Our second objective is to investigate the use of MSOT compared to duplex ultrasound and standard diagnostic work-up (including Fontaine classification) in providing more information on microvascular perfusion and oxygenation in the extremities in relation to severity of the PVD.

A total of 24 patients diagnosed with PVD (Fontaine Classification II, III, and IV) will be imaged using MSOT in this non-randomized, non-blinded, prospective, single center feasibility study. The patients will be imaged on both feet at particular landmarks, which include large arteries (arteria tibialis posterior and dorsalis pedis) and microvasculature (on each of the toes). The images will be compared to duplex ultrasound images of the large arteries, which are acquired as part of the standard of care, as well as other available diagnostic information, including the Fontaine classification.

### Study objective

Peripheral vascular disease (PVD) is a highly prevalent disease associated with significant morbidity and mortality.

Current diagnostic procedures, such as duplex ultrasound examination, are not able to visualize the direct cause of the symptoms, namely insufficient oxygenated blood perfusion of the extremities. Multispectral Optoacoustic Tomography (MSOT) is an emerging imaging technique which is capable of real-time visualization of resolving hemoglobin in its different oxygenation states and perfusion.
It is therefore hypothesized that MSOT can become a valuable diagnostic vascular imaging tool, by directly visualizing perfusion and oxygenation of blood in the extremities, as well as providing new contrast for examining blood vessels in health and disease.

**Study design**

One time-point measurement after obtaining informed consent.

**Intervention**

- MSOT imaging of the microvasculature will be performed on both feet at the arteriae tibialis posterior and dorsalis pedis, the medial side of the hallux, and plantar distal side of the phalanges.
- Pulse oximetry of each toe (10 in total) will be performed.
- The skin autofluorescence will be determined by an Advanced Glycation Endproducts (AGE) Reader and recorded.
- For comparison and validation of the MSOT images of the arteriae tibialis posterior and dorsalis pedis, duplex ultrasound imaging will be performed at these two landmarks by experienced vascular labtechnicians.
- Ankle-Brachial Index (ABI) will be measured by experienced vascular labtechnicians.
- Fontaine Classification as described in the Medical History will be recorded.

# Contacts

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# Eligibility criteria

## Inclusion criteria

- Patients attending the outpatient clinic of the vascular surgey at the Universal Medical Center Groningen.
- Age > 18 years.
- Peripheral Vascular Disease Fontaine Classification stages II, III, or IV.
- Obtained written informed consent.

## Exclusion criteria

- Medical or psychiatric conditions that compromise the patient's ability to give informed consent.
- Previous surgical or radiological treatment (percutaneous procedures with or without stenting) for PVD in the legs.
- Surgical treatment for skin abnormalities (e.g. removal of skin, skin transplants and/or tattooing).
- Active auto-immune vascular diseases.
- Lower leg fractures within the past 12 months.
- Pregnancy or breast feeding.
- (Partial) amputation of one of the legs and/or toes.

# Study design

## Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-05-2014 |

| | |
|---|---|
| Enrollment: | 24 |
| Type: | Anticipated |

## Ethics review

Not applicable

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|---|---|
| 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 | NL4308 |
| NTR-old | NTR4461 |
| Other | EudraCT number: 2014-000989-21 : CCMO-NL-48515 |

## Study results

**Summary results**

N/A.