# Clinical validation of non-invasive tissue perfusion measurements in Vascular diseased patients with PeriFlux 6000 Enhanced Perfusion and Oxygen Saturation (EPOS) system – Pilot study

No registrations found.

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

## Summary

### ID

NL-OMON27438

**Source**
Nationaal Trial Register

**Brief title**
The VEPOS study

**Health condition**

Peripheral arterial disease

### Sponsors and support

**Primary sponsor:** UMCG
**Source(s) of monetary or material Support:** Stichting lijf en leven, derde stroom

### Intervention

### Outcome measures

**Primary outcome**

To develop a standardized and optimized measurement protocol for EPOS measurements, including location on the lower leg, to optimize precision and accuracy of measurements.

### Secondary outcome

The second objective is to correlate hemoglobin oxygen saturation(%), red blood cell tissue fraction (%) and the speed resolved RBC perfusion separated into three speed regions; 0-1 mm/s, 1-10 mm/s and above 10 mm/s (% mm/s) with TcPO2 in healthy volunteers, claudicants and patients with chronic limb-threatening ischemia.

## Study description

### Background summary

SUMMARY
Rationale: Peripheral arterial disease (PAD) of the lower extremity is a progressive and common disease. Symptoms of PAD include pain during exercise, which can progress into chronic limb-threatening ischemia (CLTI) with pain at rest and non-healing ulcers. PAD and CLI are the result of impaired tissue perfusion. To determine the severity of PAD, and localize ischemic tissue, tissue perfusion measurements are necessary. Most diagnostic techniques used for the diagnosis of PAD can only detect obstruction or patency of the major arteries, and do not measure tissue perfusion. The current gold standard for non-invasive tissue perfusion measurement is transcutaneous partial pressure of oxygen (TcPO2). This method is, however, time consuming, user dependent and gives only one value for transcutaneous partial pressure of oxygen. This pilot study investigates the use of a new non-invasive modality that has the potential to increase the accuracy of determination of tissue perfusion. The Periflux 6000 Enhanced Perfusion and Oxygen Saturation (EPOS; Perimed AB, Järfälla, Stockholm, Sweden) system is a non-invasive technique which integrates the use of laser Doppler flowmetry (LDF) and diffuse reflectance spectroscopy (DRS) for the measurement of both blood flow and oxygen saturation of the microcirculation. Compared to TcPO2, EPOS may quantify severity of impaired tissue perfusion and localize regions of impaired perfusion more accurately. Therefore, it has potential as non-invasive diagnostic modality to determine indication for treatment and to determine treatment success after endovascular revascularisation procedures.
Objective: The EPOS system has not yet been CE approved, and has not been applied in clinical care. This pilot study aims to investigate the feasibility and clinical performance of tissue perfusion measurements with EPOS in the feet in 10 healthy volunteers, 10 claudicants, and 10 patients with chronic limb-threatening disease.
Study design: This study is a single center pilot study to investigate the feasibility and clinical performance of EPOS measurements in 10 healthy volunteers, 10 claudicants, and 10 patients with chronic limb-threatening disease. The tissue perfusion is measured with EPOS and TcPO2 at three different locations: plantar and dorsal surface of the foot, and gastrocnemius muscle. Skin temperature, blood pressure, and arterial oxygen saturation are also determined. Claudicants will be measured before supervised exercise, and patients with

chronic limb-threatening disease will be measured before and after endovascular revascularization. All subjects will be measured at one leg; for patients the affected leg. This is an observational study and the patients will receive diagnostics and treatment according to standard of care, which is not affected by the study results.
Study population: Inclusion criteria are age > 18 years. Ten healthy volunteers (Rutherford 0, see Table 1), 10 claudicants (Rutherford 2-3, see Table 1) and 10 patients with chronic limb-threatening ischemia (Rutherford 4-6, see Table 1) will be included in this pilot study.
Exclusion criteria are insufficient knowledge of the Dutch language, illiteracy or language barrier, severe peripheral oedema, severe cardiac-pulmonary failure, active cellulitis-erysipelas of the legs, or other dermatological diseases that would impair the measurements.
Main study parameters/endpoints: The main endpoint of this pilot study is a standardized measurement protocol for EPOS. The second study parameter is to determine baseline values of oxygen saturation, RBC tissue fraction, and speed resolved RBC perfusion, which are measured with the EPOS system, for the three groups of participants with different stadia of PAD. Factors that may affect skin perfusion will be noted, including tobacco smoking (pack years and daily consumption), coffee consumption (both global and on measurement day), daily activity (both global and on measurement day), systemic blood pressure, local skin temperature, and arterial oxygen saturation, diabetes mellitus, COPD, and cardiovascular disease.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There is very limited risk associated with participation in this study. The EPOS system is a non-invasive measurement technique which consists of the CE approved PF6001 main unit (Perimed, Järfälla, Stockholm, Sweden), including the CE-marked PF6010 LDPM/heat. The non-CE-marked PF6060 spectroscopy unit will be connected to the patient only via optical fibers and a non-CE approved EPOS probe that integrates the diffuse reflectance spectroscopy and laser doppler flowmetry. The Periflux 6000 EPOS system has been approved by the MMAC, and the study will be submitted by Perimed to the IGJ after approval of this study by the METC. TcPO2 will be measured with the PF 6040 TcPO2 unit which is a CE-approved device and will be used in this study according to intended use. Other measurements (blood pressure, skin temperature, oxygen saturation) are routine clinical measurements, with no additional risks. The burden for the participating patients consists of one or two additional measurement sessions of 100 minutes, which will be scheduled after regular care appointment when possible. Healthy volunteers and claudicants will undergo one session of 100 minutes. patients with chronic limb-threatening disease will be measured in 2 sessions, before and after endovascular revascularization. The EPOS probe has minor risk of local skin burn, as it can heat up the skin up to 44°C, which is identical to the CE-approved and commercially available PF 6040 TcPO2 and PF 6010 LDPM/Heat units. This is included in the risk assessment of Perimed, which is attached to this protocol. The study results will not affect diagnostics or treatment of the patients. There are no direct benefits for participating patients concerning the treatment they are receiving, as this study is a pilot observational study.

## Study objective

EPOS measurements are non-inferior to Tcpo2 measurements

**Study design**

January 2020 - August 2020

# Contacts

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# Eligibility criteria

## 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.
- Chronic limb-threatening disease, Rutherford classification 4 to 6

## Exclusion criteria

Healthy volunteers:
- Investigations or treatment for cardiovascular disease
- Symptoms or history of peripheral neuropathy

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.
- (Partial) amputation of one of the feet and/or legs.
- Pregnant or breast feeding.
- Severe peripheral oedema.
- Severe cardiac-pulmonary failure.
- Active cellulitis-erysipelas of the legs or other dermatological diseases.

# 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): | 13-09-2019 |
| 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 | NL8023 |
| Other | METC UMCG : 201900427 |

# Study results