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

Published: 26-11-2019
Last updated: 10-04-2024

This pilot study aims to investigate the feasibility and clinical performance of tissue perfusion measurements with EPOS in the feet/legs in healthy volunteers and patients with PAD. The EPOS system has not yet been CE approved, and has not been...

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

Summary

ID

NL-OMON48139

Source
ToetsingOnline

Brief title
The VEPOS study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Constricted bloodflow to the legs, Intermittent claudication

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting lijf en leven

Intervention

Keyword: Diffuse reflectance spectroscopy, Oxygen saturation, Peripheral arterial disease, Tissue perfusion

Outcome measures

Primary outcome

The main endpoint of this pilot study is the feasibility and clinical performance of measurement at three different locations on the foot and lower let with the EPOS system and a standardized measurement protocol for EPOS measurements.

Secondary outcome

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. 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. Other secondary goals are the comparison of EPOS measurements with tcpo2 measurements and standard non-invasive methods as skin temperature, saturation and arterial blood pressure measurements.

Study description

Background summary

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 development of non-healing ulcers. PAD and CLTI are the result of impaired tissue perfusion. To determine the severity of PAD, and localize ischemic tissue, tissue perfusion measurements are deemed necessary. Most diagnostic techniques used to establish the diagnosis of PAD can only detect stenotic lesions of the major arteries, and do not measure real tissue perfusion. Several CE-marked, non-invasive measurement techniques are available to detect tissue perfusion, but none of them has been used in the entire peri-procedural phase of PAD patients who undergo revascularisation of the lower extremity. Changes in tissue perfusion pre-, per-, post-revascularisation may be important to evaluate the clinical success of the interventions. Transcutaneous partial pressure of oxygen (TcPO2) is one of the most often used tissue perfusion techniques, but with low quality of evidence and several limitations. For example this method is operator dependent, time consuming, and not suited for everyday clinical use. 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 other imaging modalities for determination of tissue perfusion, like TcPO2, EPOS may quantify severity of impaired tissue perfusion and localize regions of impaired perfusion more accurately. An advantage of this system is the combination of DRS with LDF that not only measures hemoglobin oxygen saturation, but also the speed resolved RBC perfusion separated in three speed regions. Therefore, it has potential as non-invasive diagnostic modality to determine indication for treatment and to determine treatment success after endovascular revascularisation procedures.

Study objective

This pilot study aims to investigate the feasibility and clinical performance of tissue perfusion measurements with EPOS in the feet/legs in healthy volunteers and patients with PAD. 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 and to develop a standardized measurement

protocol for EPOS measurements.

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. Local skin temperature, systemic blood pressure, and arterial oxygen saturation with a pulseoximeter 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 most affected leg. For healthy volunteers the choice of leg will be at random. This is an observational study and the patients will receive diagnostics and treatment according to standard of care, which will not be affected by the study results.

Study burden and risks

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 (systemic blood pressure, local skin temperature, oxygen saturation) are routine clinical measurements, with no additional risks. The burden for the participating healthy volunteers and patients consists of one or two additional measurement sessions of 130 minutes, which will be scheduled after regular care appointment when possible. Healthy volunteers and claudicants will undergo one session of 130 minutes. Patients with CLTI 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 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 an observational pilot study.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

18 years and older and written informed consent with either;
- Healthy volunteer, Rutherford classification 0
- Non- critical limb ischemia, Rutherford classification 2 and 3.
- Critical limb ischemia, Rutherford classification 4 to 6.

Exclusion criteria

- 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

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	26-11-2019
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	NL70278.042.19
Other	NL8023