A multicentre study to use non-invasive methods including hyperSPECTral imaging, thermal imaging and tcPO2 for monitoring tissue perfusion in vAsCULAR patients in-hospital and at home -- The SPECTACULAR-study

Published: 16-07-2019
Last updated: 19-08-2024

Our main objective is to determine normal ranges for oxyhemoglobin, deoxyhemoglobin, oxygen saturation, local skin temperature and tcPO2 during all phases (pre-/per-/post-intervention) of treatment of peripheral arterial disease. Secondary...

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

Summary

ID

NL-OMON48324

Source
ToetsingOnline

Brief title
The SPECTACULAR-study

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: Stichting Lijf en Leven

Intervention

Keyword: Hyperspectral imaging, Non invasive diagnostic, Peripheral arterial disease, Tissue perfusion

Outcome measures

Primary outcome

The main study parameter are the longitudinal trends of oxyhemoglobin,

deoxyhemoglobin and oxygen saturation, local temperature and tcPO2 measurements

during various phases of peripheral arterial disease, pre-, per-, and

post-intervention.

Secondary outcome

Secondary endpoints in this study are, correlation between hyperspectral

imaging, thermal imaging, tcPO2 measurements and ABI, TBP and treadmill test

and degree of stenosis on CTA. Additionally, hyperspectral imaging, thermal

imaging tcPO2 measurements are associated with wound healing, clinical outcome

(increased walking distance, (re-) intervention) and origin of ulceration

(arterial or not arterial).

Study description

Background summary

Peripheral arterial disease (PAD) is a progressive and common disease. Symptoms and complications of PAD, including ulceration, are a result of impaired tissue

perfusion. To detect and determine the severity of PAD, effective diagnostics are necessary. Current diagnostic methods used for PAD can only detect arterial inflow but do not measure tissue perfusion. It is essential to determine tissue perfusion because impaired perfusion of oxygenated blood is the direct cause of symptoms. The gold standard to determine tissue perfusion is transcutaneous partial pressure of oxygen (tcPO2) measurements. However, quality of evidence for the method in PAD patients is low and the device has some limitations. For example, this method is expensive, time consuming and not suited for everyday clinical use. Hyperspectral imaging is a novel, non-invasive method to determine tissue perfusion by measuring oxyhemoglobin, deoxyhemoglobin and oxygen saturation transcutaneous. Additionally, thermal imaging is a non-invasive method to determine local changes in skin temperature, which correlates with vascular disease and ulceration. It is still uncertain, which of these devices can be used for assessment of tissue perfusion in the PAD patients. These imaging devices are hand-held and can easily be performed by health professionals in-hospital and in a home setting. This enables the use of these methods in the pre-intervention phase, during revascularisation and during the complete post-interventional follow-up. We hypothesize that hyperspectral imaging, thermal imaging and tcPO2 can be used to assess tissue perfusion during the complete care process of patients with peripheral arterial disease.

Study objective

Our main objective is to determine normal ranges for oxyhemoglobin, deoxyhemoglobin, oxygen saturation, local skin temperature and tcPO2 during all phases (pre-/per-/post-intervention) of treatment of peripheral arterial disease. Secondary objectives include, to correlate hyperspectral imaging, thermal imaging and tcPO2 measurements to standard diagnostics such as ankle/brachial index (ABI), systolic toe blood pressure (TBP) and treadmill test and degree of stenosis on CTA. In addition, to correlate hyperspectral imaging, thermal imaging and tcPO2 measurements to wound healing, to clinical outcome and to the origin of non-healing foot ulcers. Data on patient demographics, lifestyle and quality of life are also recorded.

Study design

This study is a multicentre, prospective longitudinal cohort study. Patients suspected and/ or diagnosed with peripheral arterial disease will be included. Patients who will not be diagnosed with peripheral arterial disease, will not further participate in this study. All patients diagnosed with peripheral arterial disease will receive diagnostics and treatment according to standard of care. In addition, hyperspectral imaging, tcPO2 and thermal imaging will be performed before, during, and after treatment in the patients diagnosed with peripheral arterial disease.

Study burden and risks

The risks associated in this study are very low. The HyperView hyperspectral imaging device is a CE certified, non-invasive, easy to use device. It will be used according to its intended use. tcPO2, ABI, TBP and treadmill test are routinely performed on patients with PAD. The additional measurements will be performed during normally scheduled appointments and during home visits. Patients will be asked to complete a survey three times during the study. Therefore, the burden of participating in this study is very low. There are no direct benefits for patients concerning the treatment they are receiving.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Patients who are 18 years and older with peripheral arterial disease; non- critical limb ischemia (Rutherford classification 2 and 3) or critical limb ischemia (Rutherford classification 4 to 6). Written informed consent

Exclusion criteria

Patients with insufficient knowledge of the Dutch language, illiteracy or language barrier
Patients with severe peripheral oedema.
Patient with severe cardiac-pulmonary failure
Patients with active cellulitis-erysipelas of the legs or other dermatological diseases of the legs.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2019
Enrollment:	432
Type:	Actual

Ethics review

Approved WMO

Date:	16-07-2019
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-02-2020
Application type:	Amendment
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

ID: 28679
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68848.042.19