The SPECTACULAR-study

No registrations found.

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

Summary

ID

NL-OMON28679

Source
NTR

Brief title
SPECTACULAR

Health condition

Peripheral arterial disease, PAD, Hyperspectral imaging, thermal imaging, tissue perfusion, tissue ischemia, wound healing

Sponsors and support

Primary sponsor: University Medical Centre Groningen
Hanzeplein 1, 9713 GZ Groningen
The Netherlands
Source(s) of monetary or material Support: Stichting Lijf en Leven
IJsseldijk 222, 2924 AZ Krimpen aan den IJssel

Intervention

Outcome measures

Primary outcome

To determine normal ranges for oxyhemoglobin, deoxyhemoglobin, oxygen saturation and

local skin temperature values during all stages and phases (pre-/per-/post-intervention) of treatment of peripheral arterial disease.

Secondary outcome

To provide a standardized and validated measurement protocol for hyperspectral and thermal imaging with a hand-held camera, that enables non-invasive tissue perfusion imaging at home.

To correlate hyperspectral imaging and thermal imaging with the gold standard tcPO2.

To correlate ankle brachial index (ABI), toe systolic blood pressure (TBP) and treadmill test with the gold standard tcPO2.

To associate oxyhemoglobin, deoxyhemoglobin and oxygen saturation levels and thermal imaging with:

- Clinical improvement after intervention (supervised exercise therapy, endovascular intervention or bypass surgery). Including: Multivariate analysis with patient demographics and lifestyle (data gained from a questionnaire)

- Wound healing (post-intervention and without intervention)

- Origin of non-healing ulcer (arterial, venous or neuropathic (diabetes-related)

Study description

Background summary

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, which has a crucial meaning for the clinical outcomes. 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. Therefore, we hypothesize that hyperspectral imaging and thermal imaging can be used to assess tissue perfusion during the complete care process of patients with peripheral arterial disease.

Study objective

We hypothesize that Hyperspectral imaging and thermal imaging are optimal techniques to measure tissue perfusion, and in this way diagnose peripheral arterial disease and to determine the effect of the treatment.

Study design

Before, during and after treatment.

Intervention

none

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Patients with Peripheral arterial disease, with Rutherford classification 2 to 6 and patients with undefined ulcers meet inclusion criteria.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

Patients with insufficient knowledge of the Dutch language, illiteracy or language barrier

Patients with severe peripheral oedema (will affect hyperspectral imaging and TcPO2)

Patient with severe cardiac-pulmonary failure

Patients with active cellulitis-erysipelas of the legs or other dermatological diseases (that will compromise tcPO2 of hyperspectral imaging measurements).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2019
Enrollment:	652
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48324
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7471
NTR-old	NTR7713
CCMO	NL68848.042.19
OMON	NL-OMON48324

Study results

Summary results
not applicable