The SPECTACULAR-study

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28679

Bron
NTR

Verkorte titel
SPECTACULAR

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Centre Groningen
Hanzeplein 1, 9713 GZ Groningen
The Netherlands
Overige ondersteuning: Stichting Lijf en Leven
IJsseldijk 222, 2924 AZ Krimpen aan den IJssel

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Before, during and after treatment.

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2019
Aantal proefpersonen:	652
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48324
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
not applicable