Laser speckle contrast imaging for diabetic feet

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The main objective of this study is to investigate the stability and reproducibility of the laser speckle contrast imaging (LSCI) system when applied to three groups of patients with different stages or a history of diabetic foot ulcers. Our second…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25902

Bron
Nationaal Trial Register

Aandoening

Ulcer, Diabetic foot
Wond, Diabetische voet

Ondersteuning

Primaire sponsor: ZGT Almelo - Chirurgie
Overige ondersteuning: ZGT Almelo - Chirurgie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters will be perfusion images of the diabetic foot with LSCI. The stability and intra- and inter- reproducibility of the LSCI technique will be measured and compared with non-invasive blood pressure measurements.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Diabetic foot ulcers are a major complication of diabetes mellitus, with high morbidity, mortality, healing time and costs. Healing times of diabetic foot ulcers are longest when critical ischemia is present. Critical ischemia is diagnosed by using non-invasive assessment of blood flow in the feet, by means of the ankle pressure, toe pressure or transcutaneous oxygen measurements (tcpO2). Cut-off values for these measurements are given in the international guidelines, showing the probability of healing without vascular intervention. However, current non-invasive measurement systems have various disadvantages.

Improving the diagnostic assessment of the microcirculation of the diabetic foot at the location of the ulcer is therefore needed. Laser speckle contrast imaging (LSCI) is a promising technique. The microcirculation in the outermost layers of the skin can be measured, and these measurements can be performed at the exact ulcer location. LSCI is frequently used in assessment of burns. However, it has never been applied to the diabetic foot. Results from studies applying LSCI to burns cannot be transferred to diabetic foot ulcers, as the nature of both patients with diabetes as well as the wounds are completely different. A pilot study applying LSCI to the diabetic foot is therefore needed.

Objective: Investigate the stability and reproducibility of LSCI when applied to the diabetic foot. Further, we aim to compare results from LSCI with the currently used non-invasive blood pressure measurements.

Study design: This study is a single centre observational study.

Study population: Three patients groups with diabetes mellitus (type I or type II), aged 18 years or older, with one of the following foot problems as a consequence of diabetes: Foot ulcer without (critical) ischemia (n=15); Foot ulcer and critical ischemia (n=15); or Foot ulcer history without (critical) ischemia (n=15).

Main study parameters/endpoints: The main study parameters will be perfusion images of the diabetic foot with LSCI. The stability and intra- and inter- reproducibility of the LSCI technique will be measured and compared with non-invasive blood pressure measurements.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Non-invasive blood pressure measurements will be performed and a total of four LSCI will be made. During the LSCI two occlusion tests will be performed to measure the

microcirculation of the foot and stability of LSCI. There are no known risks associated with blood pressure measurements or LSCI, beside temporary discomfort.

Doel van het onderzoek

The main objective of this study is to investigate the stability and reproducibility of the laser speckle contrast imaging (LSCI) system when applied to three groups of patients with different stages or a history of diabetic foot ulcers. Our second aim is to investigate the relation between LSCI and currently used non-invasive blood pressure measurements for the diabetic foot.

Primary Objective:
To obtain (1) the inter-subject reproducibility of LSCI, and (2) the intra-subject reproducibility of LSCI, for each group of patients separately

Secondary Objectives:
(1) To investigate the relation of LSCI and currently used non-invasive blood pressure measurements
(2) To investigate the differences in microcirculation between the three groups of patients
(3) To investigate the stability of LSCI relating to (motion) artefacts or reproducibility of occlusion tests.

Onderzoeksopzet

One measurement of approximately 60-90 minutes

Onderzoeksproduct en/of interventie

Non-invasive blood pressure measurements will be performed and a total of four LSCI will be made. During the LSCI two occlusion tests will be performed to measure the microcirculation of the foot and stability of LSCI. There are no known risks associated with blood pressure measurements or LSCI, beside temporary discomfort.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with diabetes mellitus, type I or type II

- Aged 18 years or more

- Diagnosed with one of the following foot problems as a consequence of diabetes:

(1) Foot ulcer without (critical) ischemia

(2) Foot ulcer and critical ischemia

(3) Foot ulcer history without (critical) ischemia

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Underwent (partial) amputation of foot or toes

- Infected foot ulcer

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4978
NTR-old	NTR5116
CCMO	NL52422.044.15

Resultaten