Laser speckle contrast imaging for diabetic feet

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25902

Source
Nationaal Trial Register

Health condition

Ulcer, Diabetic foot
Wond, Diabetische voet

Sponsors and support

Primary sponsor: ZGT Almelo - Chirurgie
Source(s) of monetary or material Support: ZGT Almelo - Chirurgie

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

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.

Study description

Background summary

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.

Study objective

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.

Study design

One measurement of approximately 60-90 minutes

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- Underwent (partial) amputation of foot or toes

- Infected foot ulcer

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2015
Enrollment:	45
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-03-2015
Application type:	First submission

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
NTR-new	NL4978

Register	ID
NTR-old	NTR5116
CCMO	NL52422.044.15

Study results