Photoacoustic Imaging for Diabetic Feet

No registrations found.

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

Summary

ID

NL-OMON26755

Source
Nationaal Trial Register

Health condition

Ulcer, Diabetic foot, Microcirculation,

Wond, Diabetische voet, Microcirculatie

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Department of Surgery
Zilvermeeuw 1
7609 PP Almelo
Source(s) of monetary or material Support: Ziekenhuisgroep Twente
Department of Surgery
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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

Study objective

Diabetic foot ulcers are a major complication of diabetes mellitus, high morbidity, mortality, 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 diagnostic assessment of the microcirculation of the diabetic foot is therefore needed. Photoacoustic Imaging (PAI) is a promising technique for the visualisation of blood in tissue. With PAI microcirculation in the outermost layers of the skin can be measured, and these measurements can be performed closer to the ulcer location. PAI is frequently used in assessment of microcirculation. However, it has never been applied to the diabetic foot. A pilot study applying PAI to the diabetic foot is therefore needed.

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

• Diagnosed with a diabetic foot ulcer

• Patients with diabetes mellitus, type I or type II

• Aged 18 years or more

• Presence of the hallux or second toe on both the left and the right foot for toe-pressure measurements

Exclusion criteria

• Presence of an ulcer on both feet

• Diagnosed with an 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):	01-10-2017
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48969
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6274
NTR-old	NTR6616
CCMO	NL62903.044.17
OMON	NL-OMON48969

Study results