Assessment of microcirculation in the diabetic foot with photoacoustic imaging

Published: 08-12-2017
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Investigate the stability and reproducibility of PAI when applied to the diabetic foot. Further, we aim to compare results from PAI with the currently used non-invasive blood pressure measurements.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON48969

Source
ToetsingOnline

Brief title
Photoacoustic Imaging for Diabetic Feet

Condition

- Diabetic complications
- Skin vascular abnormalities
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Diabetic foot, Ulcer

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: ZGT RVE Chirurgie

Intervention

Keyword: Diabetic foot, Microcirculation, Photoacoustic imaging

Outcome measures

Primary outcome

The main study parameters wil be the perfusion imagies accuared with

Photoacoustic Imaging and the non-invacive blood pressure measurements.

Secondary outcome

not applicable

Study description

Background summary

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 objective

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

Study design

This study is a single centre observational study.

Study burden and risks

Non-invasive blood pressure measurements will be performed and a total of eight phoacoustic images will be made. During the PAI measurements, different occlusion tests will be performed to measure the microcirculation of the foot and stability of PAI. The burden for the patients is minimal. There is no individual benefit for the patients participating in this study and it is expected that there are no risks or adverse outcomes for the subjects beside temporary discomfort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	08-12-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	01-03-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-01-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-12-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26755
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62903.044.17
OMON	NL-OMON26755