Photoacoustic Imaging for Diabetic Feet

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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...

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

Samenvatting

ID

NL-OMON26755

Bron
NTR

Aandoening

Ulcer, Diabetic foot, Microcirculation,

Wond, Diabetische voet, Microcirculatie

Ondersteuning

Primaire sponsor: Ziekenhuisgroep Twente
Department of Surgery
Zilvermeeuw 1
7609 PP Almelo
Overige ondersteuning: Ziekenhuisgroep Twente
Department of Surgery
Zilvermeeuw 1
7609 PP Almelo

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

Doel van het onderzoek

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.

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

Publiek

Ziekenhuisgroep Twente, afdeling Chirurgie

O. A. Mennes
Zilvermeeuw 1

Almelo 7609 PP
The Netherlands
088-708 3727

Wetenschappelijk

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Almelo 7609 PP
The Netherlands
088-708 3727

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Presence of an ulcer on both feet

• Diagnosed with an 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:	01-10-2017
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48969
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6274
NTR-old	NTR6616

Register	ID
CCMO	NL62903.044.17
OMON	NL-OMON48969

Resultaten