Multimodal characterization of DFUs

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An innovative wound assessment model provides a solid fundament to be able to improve interventions in DFUs. Thus, the aim of this study is to optimize, but also to assess the repeatability of a series of imaging methodologies in DFU treatment.

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

Samenvatting

ID

NL-OMON29273

Bron
NTR

Verkorte titel
CHDR1857

Aandoening

Wound healing

Ondersteuning

Primaire sponsor: CHDR
Overige ondersteuning: CHDR

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Efficacy endpoints
Characterization of the DFU / healthy control by:
- Clinical imaging: 2D and 3D photography, laser speckle contrast imaging (LSCI), trans epidermal water loss (TEWL),

thermography, optical coherence tomography (OCT), handheld duplex ultrasound and digital subtraction angiography (DSA) of
the arteries of the lower limb
- Clinical evaluation: Red-Yellow-Black (RYB) wound assessment scale, WIfI classification system, PEDIS score system, TIME
wound assessment and toe systolic pressure (TP) measurement

Tolerability / safety endpoints
- Adverse Events (AEs)
- Only for patients:
o Tolerance (Red-Yellow-Black (RYB) wound assessment scale, WIfI classification system, PEDIS score system, TIME wound
assessment)
This is a study using non-invasive assessment methods without the need for contrast imaging. Since the primary aim of this study is wound characterizat¡on, we foresee no adverse events related to the methodology assessments. However, at all times during the study, patients and subjects will be monitored forthe presence of any adverse events. Any relevant conditions or diseases that arise during the study period will be documented.
Secundary study parameters/outcome of the study (if applicable)

Toelichting onderzoek

Achtergrond van het onderzoek

Endovascular revascularization plays an important role in the wound healing process, but its appropriate first-line strategy for employment is not yet established. Moreover, it is unclear which patients benefit from angioplasty. It is suspected that a revascularized lower leg artery generally
remains patent for at least 6 weeks and that this provides a sufficient boost to realize wound healing. However, the knowledge of the exact effects of angioplasty and the actual redeemed perfusion of the local vascular territory of the ischemic DFU is very limited. In order to gain more
insight into the long-term effects of revascularization of DFUs, a complete wound assessment can provide more information and new perspectives in the treatment of such wounds. Combining multiple interdisciplinary tools provides the opportunity for such assessments. This combined set of
imaging and assessment methodologies can, in a later stage, be used to research novel wound treatment opportunities.

Doel van het onderzoek

An innovative wound assessment model provides a solid fundament to be able to improve interventions in DFUs. Thus, the aim of this study is to optimize, but also to assess the repeatability of a series of imaging methodologies in DFU treatment.

Onderzoeksopzet

Day 0 - EOS

Onderzoeksproduct en/of interventie

N.A.

Contactpersonen

Publiek

Centre for Human Drug Research
Danielle Koeman

+31 71 5246 400

Wetenschappelijk

Centre for Human Drug Research
Danielle Koeman

+31 71 5246 400

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible patients must meet all of the following inclusion criteria at screening:
1. Male and female patients with ischemic or neuro-ischemic DFUs, ≥18 years of age.
2. Type 1 or type 2 diabetes mellitus with either oral hypoglycaemic medication and/or insulin treatment. Any other clinical significant active or uncontrolled chronic disease than diabetes mellitus will be recorded.
3. Suitable DFU(s) for performing assessments as judged by the investigator or medically qualified designee.
4. Planned to receive PTA by standard care practice protocol.
5. Willing to give written informed consent and willing and able to comply with the study protocol.

Healthy volunteers
Eligible gender, age, BMI, and ethnicity-matched healthy subjects must meet all of the following inclusion criteria at screening:
1. Healthy subjects, male or female, ≥18 years of age. The health status is verified by absence of evidence of any clinical significant active or uncontrolled chronic disease following a detailed medical history and a complete physical examination including vital signs. In the case of uncertain or questionable results, tests performed during screening may be repeated before randomization to confirm eligibility or judged to be clinically irrelevant for healthy subjects.
2. Willing to give written informed consent and willing and able to comply with the study protocol

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Eligible patients must meet none of the following exclusion criteria at screening:
1. Presence of wounds other than non-healing amputation wounds or DFUs (e.g. due to trauma, ingrown toenails, or tophaceous gout).
2. Have any current and/or recurrent pathologically relevant skin or vascular condition other than chronic vascular insufficiency.
3. Any (medical) condition that would, in the opinion of the investigator, potentially compromise the safety or compliance of the subject or may preclude the subject's successful completion of the clinical trial.

Healthy volunteers
Eligible gender, age, BMI, and ethnicity-matched healthy subjects must meet none of the following exclusion criteria at screening:
1. Presence of wounds on legs or feet.
2. Have any current and/or recurrent pathologically relevant skin or vascular condition.
3. Participation in an investigational drug or device study within 3 months prior to screening or more than 4 times a
year.
4. Use of topical medication (prescription or over-the-counter (OTC)) within 30 days of the start of the study in
local treatment area (legs and feet).
5. Any (medical) condition that would, in the opinion of the investigator, potentially compromise the safety or
compliance of the subject or may preclude the subject's successful completion of the clinical trial.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	31-08-2019
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N.A.

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52900
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8169
CCMO	NL69946.098.19
OMON	NL-OMON52900

Resultaten

Samenvatting resultaten
N.A.