An observational study to characterize chronic wounds in patients with diabetic foot ulcers (DFUs)

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Primary Objectives- To objectively quantify the spatial and temporal kinetics of perfusion and wound healing using clinical imaging and evaluations between diabetic wounds before and after endovascular revascularization and between diabetic patients...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON52900

Source
ToetsingOnline

Brief title
Multimodal characterization of DFUs

Condition

- Epidermal and dermal conditions

Synonym
Wound healing

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: CHDR

Intervention

Keyword: Characterisation, Diabetic foot ulcers, Wounds

Outcome measures

Primary outcome

Efficacy endpoints

Characterization of the DFU / healthy control by:

- Clinical imaging: 2D and 3D photography, LSCI, TEWL, thermography, OCT, duplex ultrasound and DSA of the arteries of the lower limb

- Clinical evaluation: RYB wound assessment scale, WIfI classification system, PEDIS score system, TIME wound assessment and TP measurement

Tolerability / safety endpoints

- AEs

- Only for patients:

o Tolerance (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 is the wound characterization the treatment is not considered to be investigational in the strict sense of the protocol. Therefore, we foresee no AEs related to the protocol-related methodology assessments.

Secondary outcome

N.A.

Study description

Background summary

The worldwide population of diabetic patients and associated consequences, including a diabetic foot ulcer (DFU), is rapidly increasing.
Endovascular revascularization plays an important role in the wound healing process, but its appropriate first-line strategy for employment is not yet established. 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.

Study objective

Primary Objectives
- To objectively quantify the spatial and temporal kinetics of perfusion and wound healing using clinical imaging and evaluations between diabetic wounds before and after endovascular revascularization and between diabetic patients and healthy volunteers.
Secondary Objectives
- To characterize and monitor wound healing in DFUs after endovascular revascularization.
- To assess by multiple non-invasive modalities the local perfusion of feet, legs, and (non-healing amputation) wounds expressed in pixel density and its correlation with toe systolic pressure, duplex ultrasound and digital subtraction angiography.
- To explore the correlation between revascularization and the change in pixel density measured over time.
- To assess the reliability and repeatability of measurements in healthy volunteers.
- To monitor for the presence of any tolerability or safety signals.

Study design

This is a multicenter observational cohort study.

Study burden and risks

There is insufficient knowledge on the effects of revascularization to determine if this procedure will induce (complete) wound healing in individual patients. This study provides an opportunity to investigate and quantify the effects of revascularization on the recovery of DFUs over 90 days. In wound

healing, 90 days can be considered long term since normal wounds generally enter the remodelling phase after 21 days. Therefore, following the process of wound healing after PTA will yield valuable information for the improvement of standard care. Participating in this study has no specific direct benefits for the individual subject. Due to the non-invasive character of this study, risks are considered to be very minimal. An allergic reaction to ultrasound gel could be a potential but extremely rarely happening risk.

Contacts

Public
Centre for Human Drug Research

Zernikedreef 8
Leiden 2333CL
NL
Scientific
Centre for Human Drug Research

Zernikedreef 8
Leiden 2333CL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients
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.

Exclusion criteria

Patients
Eligible patients will be excluded if any of the following exclusion criteria apply 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 will be excluded if any of the following exclusion criteria apply 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-10-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	19-06-2020

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	02-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-08-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 29273
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL69946.098.19
OMON	NL-OMON29273