'Proof of concept study of the apllication of Active Chlorine in patients Treated for Chronic Leg Ulcera to speed up reepithelialisation' (ACTCU)

Published: 19-12-2022
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What is the effect in reepithelialisation of chronic ulcers using hypochlorous acid solution during 6 weeks.

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

Summary

ID

NL-OMON51522

Source
ToetsingOnline

Brief title
ACTCU

Condition

- Epidermal and dermal conditions

Synonym
legulcer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: geen financiering

Intervention

Keyword: active, chlorine, legulcer, reepithelialisation

Outcome measures

Primary outcome

What is the effect in reepithelization of chronic ulcers using hypochlorous

acid solution during 6 weeks.

Secondary outcome

The amount of patients with a >50% reepithelialisation at week 6.

• The change in reepithelialisation measured at all visits from baseline till

week 6.

• The reduction in VAS pain score measured at all visits from baseline till

week 6.

• The change in pain score measured at all visits from baseline till week 6.

Study description

Background summary

n dermatology practice a large group of patients is suffering from chronic slow-healing wounds from different origins, like venous diseases but also due to trauma. One of the characteristics of these wounds is that they are colonised by bacteria and fungi which inhibit the reepithelialisation and healing process.

Active chlorine released from hypochlorous acid solution is very effective against bacteria and candida species at relatively low concentrations.

A decrease of bacterial and fungal load in these chronic slow-healing wounds has a positive effect on the healing time of these wounds. A fast recovery will reduce the amount of pain and discomfort experienced by patients. Additionally, this could result in a reduction of healthcare costs associated with ulcers.

Study objective

What is the effect in reepithelialisation of chronic ulcers using hypochlorous acid solution during 6 weeks.

Study design

The study will be performed as a single arm interventional study in which ten patients with chronic ulcer(s) (more than 6 weeks present despite normal wound care provided by GP or home care)

Study burden and risks

not applicable

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

leg ulcus consisting over 6 weeks other than exclusivly arterial ulcers

Exclusion criteria

• Age younger than 18 years
• Suffering from somatic or psychiatric disease which makes it impossible to come to our outpatient clinic
• Suffering from complicating diseases which also interfere with wound healing

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-05-2024
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	active chlorine generated from hypochlorous acid
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	19-12-2022
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL80387.099.22