Wireless Micro Current Stimulation: adjunctive therapy for hard-to-heal chronic wounds * a double-blind, placebo controlled trial

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Our aim is to determine whether Wireless Micro Current Stimulation accelerates wound healing in hard-to-heal chronic wounds as compared to standard wound care treatment by conducting a double-blind, placebo controlled trial.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON44959

Source
ToetsingOnline

Brief title
Placebo Wireless Micro Current Stimulation/Placebo-WMCS

Condition

- Skin and subcutaneous tissue disorders NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
Diabetic ulcer, pressure sores/decubitus

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Researchfonds Bronovo

Intervention

Keyword: Adjunctive wound treatment, Hard-to-heal chronic wounds, Placebo controlled trial, Wireless Micro Current Stimulation (WMCS)

Outcome measures

Primary outcome

Our main study parameter will be the monthly wound area reduction during the

maximum study related treatment of twelve weeks.

Secondary outcome

Secondary outcomes are: days upon full epithelisation of the wound surface,

pain reduction, complications compared to contemporary wound therapies, a

monthly Patient Related Outcome Measure and a cost-effectiveness analysis from

a healthcare perspective.

Study description

Background summary

Wireless Micro Current Stimulation (WMCS) is a new method within Electric Stimulation (ES) therapy. It allows contactless wound treatment and stimulates the healing process through the induction of the natural *current of injury*. It uses the capacity of nitrogen and oxygen to donate electrons, thereby surpassing expensive and cumbersome electrodes and devices. This simple noninvasive technology has had astounding results in recent studies and is assumed not only to have a huge potential to recalcitrant wounds but also to treat chronic wounds generally. It could prove to have a transformative effect on the treatment of chronic with significant cost reduction.

Study objective

Our aim is to determine whether Wireless Micro Current Stimulation accelerates wound healing in hard-to-heal chronic wounds as compared to standard wound care treatment by conducting a double-blind, placebo controlled trial.

Study design

This study will be a double-blind, randomized, placebo controlled trial conducted within Haaglanden MC, The Hague and Erasmus MC, Rotterdam. Patients that already received 4 weeks of once weekly standard wound care treatment during outpatient control are randomised for placebo-controlled WMCS treatment thrice weekly for 45 minutes. The placebo WMCS device is indistinguishable from the original WMCS device.

Intervention

All subjects will receive (placebo) WMCS treatment thrice weekly for 45 minutes per session during the maximum study related treatment of twelve weeks while using the same dressings as received during once weekly standard outpatient wound care. All data prior to the start of (placebo) WMCS treatment will be used as control group data.

Study burden and risks

During the start of the therapy patients may report a minimal burning sensation or itch at the treatment area, but no side effects or complications have been reported. Pain medication has never been administered within the recent studies and no change of the surrounding healthy tissue has been observed.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age of 18 years and older
- Mentally competent
- Ankle-brachial index between 0.7-1.2
- In case of patients with diabetes: toe systolic pressure should be above 50mmHg
- Signed the informed consent form
- Hard-to-heal chronic wound as defined: Wounds existing over six weeks with a biological or physiological reason for stagnation of the healing process, such as diabetic ulcers, arterial or venous ulcers and pressure sores on the lower extremity with failure to achieve the expected wound healing progress with the use of standard outpatient wound care.

Exclusion criteria

- Pregnancy
- (Cardial) Implanted electrical device
- (Skin)malignancy within the therapeutic range.
- Epilepsy
- Overshoot granulation tissue of the wound
- Severe woundinfection
- Any treatment with metal ion-containing wound care products
- Ankle-brachial index <0.7 or >1.2
- In case of patients with diabetes: toe systolic pressure <50mmHg

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2015
Enrollment:	34
Type:	Actual

Medical products/devices used

Generic name:	Wireless Micro Current Stimulation (WMCS)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-05-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	05-08-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	19-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	15-11-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	09-01-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL52982.098.15