Wireless Micro Current Stimulation: adjunctive therapy for acute and chronic wounds * a randomized controlled trial.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41079

Source
ToetsingOnline

Brief title
Wireless Micro Current Stimulation/WMCS

Condition

- Other condition
- Skin and subcutaneous tissue therapeutic procedures

Synonym
Diabetic ulcer, pressure sores/decubitus

Health condition

Wondzorg

Research involving
Human

Sponsors and support

Primary sponsor: Bronovo Ziekenhuis
Source(s) of monetary or material Support: Researchfonds Bronovo

Intervention

Keyword: Acute and chronic wounds, Adjunctive wound treatment, Electrical stimulation (ES), 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 three months. Secondary outcomes are: days upon full epithelisation of the wound surface, pain reduction, complications compared to contemporary wound therapies, Patient Related Outcome Measure and a cost analysis on nursing costs and dressing.

Secondary outcome

Secondary outcomes are: days upon full epithelisation of the wound surface, pain reduction, complications compared to contemporary wound therapies, Patient Related Outcome Measure and a cost analysis on nursing costs and dressing.

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 wound current. 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 wounds and burns with significant cost reduction.

Study objective

Our aim is to determine whether Wireless Micro Current Stimulation accelerates wound healing in chronic wounds as well as surgical wounds healing by secondary intention, as compared to standard treatment. Furthermore, by usage evaluation we intend to ascertain whether WMCS could be applied in an outpatient environment due to potentially similar effectiveness across varying treatment times.

Study design

This study will be a prospective randomised controlled trial conducted within Bronovo Hospital and Sophia Revalidatie, The Hague and may extend to include Medisch Centrum Haaglanden, The Hague.

Intervention

Patients randomised to WMCS will receive treatment thrice weekly for 45 minutes per session. In case of a chronic wound an extra randomisation takes place to vary the treatment algorithm once weekly for 45 minutes, twice weekly for 45 minutes, thrice weekly for 45 minutes or thrice weekly for 30 minutes. Patients are otherwise treated with the same dressings and intervals as they would have done, or as if they had been randomised to the control group.

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

Age of 18 years and older
Mentally competent
Signed the informed consent form
Secondary healing surgical wound or chronic wound as defined:
o Acute: natural intended closure of a surgical/traumatic wound, for example post-operative pilodinal sinuses, split skin grafts (SSG), second degree burns, dehiscent wounds or contaminated cutting wounds at the E.R. with conventional wound care methods during follow-up.
o Chronic: 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 or decubitus

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	450
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Date:	27-11-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Not approved

Date:	26-03-2015
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	NL50699.098.14