Draadloze Elektrostimulatie: een aanvullende behandeling voor recalcitrante chronische wonden - een dubbel-blinde, placebo gecontroleerde studie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22095

Source
NTR

Brief title
Placebo-WMCS

Health condition

English:
- Chronic wound
- Arterial ulcer
- Venous ulcer
- Diabetic ulcer
- Electroceutical
- Electrical stimulation

Dutch:
- Chronische wond
- Arterieel ulcus
- Veneus ulcus
- Diabtisch ulcus
- Electroceuticals

- Elektrische wondstimulatie

Sponsors and support

Primary sponsor: Department of plastic-, reconstructive- and hand surgery, Haaglanden Medical Centre, The Hague
Source(s) of monetary or material Support: Bronovo Research Fund, The Hague https://www.bronovo.nl/vrienden-van-bronovo/projecten/onderzoek

Intervention

Outcome measures

Primary outcome

Monthly wound area reduction during the maximum study related treatment of three months

Secondary outcome

- Weekly wound area reduction

- Days upon full epithelisation of the wound surface

- Adverse events

Study description

Study objective

Wireless Micro Current Stimulation (WMCS) accelerates wound healing in hard-to-heal chronic wounds compared to standard wound care.

Study design

- Weekly wound photography (minimum 4 weeks prior)

- Baseline characteristics

- Weekly wound photography (maximum 12 weeks during)

- Follow-up: 1,3 and 6 months

Intervention

All subjects will receive (placebo) WMCS treatment thrice weekly for 45 minutes per session during the maximum study related treatment of three months 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.

Contacts

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Eligibility criteria

Inclusion criteria

- Age: 18 years and older

- Mentally competent

- Ankle-brachial index between 0.7-1.2

- In case of diabetes: toe systolic pressure >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, need for antibiotics

- 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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-09-2015
Enrollment:	42
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-05-2017
Application type:	First submission

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
NTR-new	NL6276
NTR-old	NTR6450
Other	NL52982.098.15 : CCMO

Study results