The QWhet micro current wound stimulator, evaluation of efficacy and side effects

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

Summary

ID

NL-OMON55801

Source
ToetsingOnline

Brief title
The QWhet study

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
Chronic wounds, open wounds existing for more than 3 weeks

Research involving
Human

Sponsors and support

Primary sponsor: Q Care Medical Services B.V.
Source(s) of monetary or material Support: Q Care Medical Services BV

Intervention

Keyword: chronic wound, micro current, Q-whet, wound stimulation

Outcome measures

Primary outcome

Percentage of patients with an ADE after 28 days of treatment with QWhet.

H0: percentage of patients is larger than 5%.

Ha: percentage of patients is less or equal to 5%.

Secondary outcome

The average percentage woundsurface area (length x width) reduction as compared

to baseline after 28 days of treatment with QWhet.

H0: average percentage woundsurface reduction less than 33% compared to baseline

Ha: average percentage woundsurface reduction at least 33% compared to baseline

Study description

Background summary

Applying electrical currents for wound healing is not new, al lot of studies (see literature overview) have been published proving the efficacy of the therapy. The most promising current type is the 'micro current' because of its similarity to the natural healing process.

Several companies have such devices already in the market to treat sub-acute and chronic wounds. Their devices are often bulky and heavy and are complex to operate. These devices also need a power outlet, so the patient loses mobility as long as the treatment is given (several hours a day is necessary). The current is applied by using standard hydrogel electrodes around or outside the wound. Because the human body is not a perfect conductor it*s not guaranteed that the current actually will go through the desired wound area and have

therefore less efficiency. Wound care specialists searched therefore ways to to get the current inside the wound. In many cases by using very moist dressings and use the conductive hydrogel electrode on top of these moisturized dressings. The preparation and extra handling of these wound dressings also creates an higher risk of infection.

The Q-Whet wound stimulator gives a solution to all this: it*s small, light, portable and battery operated. There is just one activation button and the software of the device detects automatically whether there is an internal wound pad or 2 external pads attached. The patient is maximally mobile and wound therapy can last 24 hours per day. The micro current is theoretically not noticeable by the patient.

Study objective

The aim of this study is to assess the effects and side effects of the QWhet micro current wound stimulation device in up to 78 subjects with a chronic wound over a continuous period of 28 days.

The collected (coded) data will be used by Q Care to get CE mark for the QWhet.

Study design

The QWhet study is a premarket, prospective, single-arm, single-center study. A maximum of 78 participants with a chronic wound (existing longer than 3 weeks) will be treated with a wound stimulator in the wound (internal wound pad) for 28 days.
At the start of the study on day 0, a questionnaire, including VAS and EQ5D, is completed by the study participant and wound nurse, then every 7 days (days 0, 7, 14, 21 and 28).

Intervention

The intervention consists solely of adding the QWhet stimulator to the standard wound treatment.

Study burden and risks

Risks:

INFECTION: low

The internal pad are sterile packed. The specialised wound care nurse is trained to apply these materials in a sterile fashion. The package of the Q-Whet wound stimulator contains an elaborate information brochure for the the wound care nurse. Before start of the study the wound care nurse will also

recieve a training on how to use the device.

The chances of infection caused by the Q-Whet wound stimulator is low.

ALLERGIC REACTION: low

The internal wound pad is a very thin cloth with a conducting layer fo aluminum oxide. All needed tests on allergic reactions have been done. Up to now, no allergic reaction has been registered.

Chances on an allergic reaction are low.

ELECTRICAL CURRENT: none/very low

The current used of 200-800 micro Ampere during a period of a maximum duration of 30 days is provided by a small watch battery. This current is low and theoretically not detectable by a patient. In comparison the current used in a TENS muscle stimulator is 15 milli ampere, more than 18 times the current in the Q-Whet wound stimulator.

Chances on adverse reactions by electrical current are none/very low

HARDWARE Q-WHET WOUND STIMULATOR: low

The hardware of the Q-whet wound stimulator is a small and light plastic box (7*5*2 cm). This box sticks tot the skin with an adhesive tape or can be integrated into the bandage around the wound. If an allergic reaction would occur, the hardware can be shifted to another location on the body.

Chances on an allergic reaction is low.

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

- Patients with chronic wounds (at least 3 weeks old)
- age older than 18 years
- able to understand and willing to fill out questionaires

Exclusion criteria

1. pregnancy and lactation
2. Use of other internal electronic devices (e.g., pacemaker, internal defibrillator)
3. mental retardation
4. fever (above 38.5 degrees Celsius)
5. Active wound infection, to be assessed by the physician investigator on clinical grounds
6. under the age of 18 years
7. wounds with necrotic tissue
8. carcinoma or melanoma in the wound or adjacent skin
9. untreated osteomyelitis of the wound
10. allergy to aluminum
11. chronic wound located on the head, neck or on the thorax
12. participation in an investigational medicine or medical device study of which the primary end point has not been reached yet
13. any other condition which, at the discretion of the physician, may prevent successful completion of the study.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2022
Enrollment:	78
Type:	Actual

Medical products/devices used

Generic name:	QWhet micro current wound stimulator
Registration:	No

Ethics review

Approved WMO Date:	20-03-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-04-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-03-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL69453.028.19