CE marking for the Q-whet micro current wound stimulator

Published: 29-06-2018
Last updated: 11-04-2024

Objective:The objective of the study is to test the hypothesis that the QWHET micro current wound stimulation device has minimal side effects. The study will be designed as a double blind, prospective study.The results will be used to obtain a CE...

Ethical review	Not approved
Status	Will not start
Health condition type	Procedural related injuries and complications NEC
Study type	Observational non invasive

Summary

ID

NL-OMON45773

Source
ToetsingOnline

Brief title
CE marking for the Q-whet micro current wound stimulator

Condition

- Procedural related injuries and complications NEC
- Skin and subcutaneous tissue disorders NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
chronic wounds

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Bedrijf: Q-Care medical services;Oisterwijk;Nederland

Intervention

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

Outcome measures

Primary outcome

Patient related parameters (at time point 0,7,14,21,28 days of treatment)

1. Pijn:

- bij aanbrengen QWHET

- bij dragen van QWHET

- bij verwijderen van QWHET

- verschil van pijn tussen wel en niet aangeschakelde QWHET

2. Gebruiksvriendelijkheid:

- formaat

- beperking in bewegingsvrijheid

- duidelijkheid van handleiding

Wound consultant (op tijdstip 0,7,14,21,28 dagen behandeling)

1. Is user manual clear

2. Is the device easy to apply

3. are wound pads easy to apply

3. is wound pad easy to apply

4. are the devices easy to remove from sterile packaging

5. are the connectors easy to insert into device

6. is it easy to combine with the standard wound therapy

Wound (op tijdstip 0,7,14,21,28 dagen behandeling)

1. is there an allergic reaction to the pads

- pad for device

- skin pads

- wound pad

2. any adverse reaction (op tijdstip 0,7,14,21,28 dagen behandeling)

- itching

- fever

- enlargement wound

- exaggerated wound infection

- failure to treat wounds for the whole period of 28 days (reason?)

Secondary outcome

Questionnaire for wound consultant (op tijdstip 0,7,14,21,28 dagen behandeling)

Does the treatment has any effect on wound healing:

- size

- deepness of wound

- vascularisation

- pain

- irritation

Study description

Background summary

Device novelty

Applying electrical currents for wound healing is not new, al lot of studies have been published proving the efficacy of the therapy . The most promising current type is the micro current because of its similarity with 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. But this is a time consuming process and time is something a
care taker doesn*t have when visiting patients. The preparation and extra handling of these
wound dressings also creates an higher risk of infection.

QWHET gives a solution to all this: it*s small, portable, battery operated there is no need forconfiguring and it uses a unique developed sterile wound electrode that can be placed inside the wound. The QWHET stimulator differs from these devices in its approach because it has the
following properties:
* It uses a unique developed sterile wound electrode that can be placed inside the wound (where it*s the most effective).
* It is portable and battery operated therefore no connection to the mains supply
which results in a greater mobility for the patient.
* It uses only micro currents because its well-researched and

-documented
* It*s small (can be worn concealed * no stigma)
* It has no control buttons, does not need to be configured. This reduces the
necessary installation time and hazardous situations while applying the device.

Configurations
The device is delivered in two configurations
* for treatment inside the wound
* for treatment next to the wound on intact skin
Once the device is applied on the patient and the electrodes are connected, the device starts
generating an ultra-small electrical current. This current mimics the healing current of the human body(current of injury). Studies show that a micro current below 1000*A increase the ATP adenosine triphosphate substantially.

The device consists out of 3 major parts
* Stimulator
* Pad electrode
* Wound electrode

Stimulator:

The stimulator is for single patient use, the electrodes are for single use only. The device is battery operated (coin cell). The device cannot be opened so the battery cannot be replaced. The device should be applied by a registered wound care expert the patient does not apply the device.
There are 2 micro current output channels. On the micro current output channels A and B, 2 types of electrodes can be used;
* the WOUND electrode
* The SKIN electrode

The Stimulator can detect if the SKIN electrode or the WOUND electrode is connected. The device communicates with the user by means of a very simple user interface; 3 LED*s and 1 buzzer. Via the LEDs and the buzzer, the user gets information about:
*the status of the battery,
*if the electrodes are making contact,
*if the therapy is active or ended.

De PAD electrode

This PAD electrode is the common electrical electrode; it*s a

standard hydrogel electrode. On the (non-conductive) top side of the electrode there is an adhesive area non-conductive side where the device can be placed on after the protective layer is removed. When the device is placed on the adhesive side of the PAD electrode and the connector is inserted in the device , it switches in standby mode.

USED MATERIAL SKIN AND PAD ELECTRODE
The SKIN and PAD electrodes are standard available hydrogel electrodes. They hydrogel layer of the electrodes is in contact with the patients intact skin.

USED MATERIAL WOUND ELECTRODE
The WOUND electrodes is developed in house by QCARE. the production is outsourced by a certified subcontractor. The monofilament yarn is coated with a thin (*m) layer of aluminum to make the textile electrical conductive.

SKIN and PAD Electrode have been tested on Cytotoxicity, Primary Dermal Irritation, Delayed Contact Hypersensitivity as suggested by FDA and ISO 10993-1 see *RG-63B Hydrogel Final Biocompatibility Report*

Study objective

Objective:

The objective of the study is to test the hypothesis that the QWHET micro current wound stimulation device has minimal side effects. The study will be designed as a double blind, prospective study.The results will be used to obtain a CE marking.

(Future: After obtaining the CE marking, an additional study will be implemented to test clinical efficacy on wound healing)

Study design

The study will be designed as a double blind and prospective study. For this study we will need 30 patients who will use the QWHET system for a period of 28 days. Before the study, the patient has to sign a informed consent form.

The 30 patients will be divided in 2 groups of 15 patients, group 1 and 2. Group 1 will receive the QWHET with the skin electrode and group 2 the wound pad.

Both groups will receive wound treatment every 5 days when the device will be changed for a new one. The investigator does not know if it is an active or a non-active device. The devices will be internally modified by the manufacturer to be an active or non-active device. Only after the study the assignment of the devices will be revealed for data processing.

At each visit for the change of the device, a questionnaire will be filled out by the wound consultant or investigator and a separate one by the patient. Also at the end of the study a questionnaire will be filled out.

Study burden and risks

Summary of the risk analysis

Most of te risks are related to the fact that a contaminated wound electrode can cause an infection to the patient. Chronic, delayed or complex wounds are wounds that do not heal at all or they do not heal within a normal woundheal period of 4 to 6 weeks. In most cases this is caused by an infection of the wound. In our risk analysis, we estimated this risk as serious to severe. When the electrode and stimulator is appropriately applied, the risk towards the patient and the operator is low because we use registered woundcare experts who are trained in standard woundcare protocols and who know how to handle sterile products and to apply. The patient does not apply the product. The intensity of the current that is generated out of the coin battery is so low that no hazardous situation can arise. The applied micro current is between 200 *A and 800*A and for the patient not noticable.

For muscle stimulators that cause contractions work in the mA range (starting at 15mA), it is suggested that a current density of no more than 0.5mA/cm² is applicable at the negative(cathode) electrode and 1.0mA/cm² at the positive(anodal) electrode. Above this value tissue damage, and especially skin burn, may occur (only with direct current types).

The wound electrode has a current more than 130 times lower and therefore not dangerous for the patient.

Results of the risk assessment
As a result of the risk analysis we decided that the biggest risk lays in the use and production of the wound electrode. The following measures have been taken. The device will be sold to wound care organizations (ex.: Q Care medical services BV The Netherlands). These organizations have wound care specialist who know exactly how to take care of wounds and wound healing. They use already sterile wound care dressings so they know how to handle them. So placing

the electrode in the wound in such a way that no contamination can occur is standard practice for them. Because this action bears the highest risk we gave special attention to this in the user manual. The operators are registered wound care specialists, they have an educational level that lets us conclude that they can interpret the given safety info in the manual and on the labeling of the device. Because the device is so simple to operate, only the electrodes need to be connected to the device (comparable to charging a cell phone), we don*t see any elevated risks here.

Production of the electrode

Our subcontractor has an ISO13485 QMS and has already experience in producing wound care products in clean room (Class ISO7). They all have the necessary experience, they develop and produce wound care products for the biggest companies active on the wound care market. These companies audit the organization on a regular basis. Selecting such a partner assures us that the risk of contamination in production is minimized. Q Care will audit the critical suppliers on a regular basis and all critical suppliers have signed our quality agreements.

Anticipated risks, contra-indications, warnings

Based on the QWHET Risk Analysis and the experience of our wound care specialists. The following contra indications have been defined for patient as for the practitioner. Wound care specialists will have to consider the patients* conditions to decide whether or not to use QWHET. They will also have to make the decision if QWHET should be used outside the wound with the normal hydrogel electrodes or inside the wound with the QWHET wound electrode.

During the treatment periode of maximum 30 days the wound electrode will be replaced each time the standard wound dressings are replaced (typically every 3 to 5 days depending on the judgement of the wound care specialist). The WOUND electrode is single use and the wound care specialist will also need to observe and report any abnormalities during the treatment as usual and give approriate information to the patient as well. QWHET should be kept out of the reach of children.

QWHET should not be used
*Where there is a carcinoma or melanoma in the wound or adjacent skin
*On wounds with necrotic tissue (use after debridement)
*Where there is untreated osteomyelitis of a wound.(might cause early closure of

the soft tissue prior to resolution of the osteomyelitis, leading to potential abscess formation)
*On cardiac pacemaker and metal implant patients.
*Until etiology is established.
*During pregnancy, delivery and lactation
*Combined with other electronic monitoring or stimulation equipment (such as ECG).
*If patients start to experience skin irritation or hypersensitivity.
*On cancer patients and lower motor neuron damage individuals.
*On patients allergic to aluminium.
*On patients younger than 18 year.
*During medical visual examinations (MRI/ECG/EEG....)
*Combined with other electrical based high energy examination or therapy techniques.

QWHET electrodes should not be placed
*across the carotid sinus (neck region), in such a way that current flows through the
head

Conclusion
Looking at the measures and the actions taken during the development and production of the device and executing the risk analysis like described in QWHET Risk Analysis v01_20170622. The management of Q Care Medical Services has concluded that the overall residual risk posed by QWHET is acceptable.

Product verification and validation

Biocompatibility
As a result of the conducted risk analysis and the intended use, it is necessary to perform biocompatibility tests to proof the patients safety when using the SKIN, PAD and WOUND electrodes. All referenced documents can be found in the Technical Dossier.

Only the electrodes come in contact with the patients skin, the PAD and SKIN electrode are placed on intact skin, the wound electrode in contact with breached skin.

The conductive hydrogel layer of the SKIN and the PAD electrode comes in contact with intact skin. These electrode types are well known and distributed on the European market by Peppin Mfg. They are used for ECG, EEG, EMG recording or for muscle stimulation in physiotherapy revalidation. Peppin creates an OEM version for QCARE where non crucial parameters are customized for QCARE (size, printing, connector, ..) the crucial component, the hydrogel layer, in contact with the human body are standard and already in use in

their CE certified products.

Biocompatibility of the hydrogel layer is tested

SKIN and PAD Electrode have been tested on Cytotoxicity, Primary Dermal Irritation, Delayed Contact Hypersensitivity as suggested by FDA and ISO 10993-1 Hydrogel Final Biocompatibility Report*

WOUND electrodes

Since the circular (wound contact area) part of the wound electrode is placed on top or inside the chronic wound, the wound textile comes in contact with breached skin or the wound bed. This textile is wound care material from the company SEFAR. They have a textile mesh called COMPRESS MESH-FIX that is placed on the wound bed to prevent other used wound dressings to grow into the wound. This product is manufactured in cleanroom The textile shape is cut out according the specifications of QCARE, to make the textile electrical conductive the material is covered with extremely thin aluminum layer.

Sensitisation and irritation used standards ISO 10993-5, ISO 10993-10, OECD TG 422C, OECD No. 4

Conclusion

Based upon consideration of the overall results of this reports Q Care Medical services concludes that the used Qwhet WOUND, SKIN and PAD electrodes meet the requirements and are safe to use on patients. Reaction from the market related to the use of the electrodes will be followed up closely via the post market surveillance.

Sterilisation
The wound electrodes will be sterilised by the company Rose gmbh. The electrodes used in this clinical evaluation will be ETO sterilised during a sublethal test.

Electrical / mechanical safety
Because the device is classified as an active device, it was tested against; electrical safety mechanical safety and electrical compatibility. The following standards have (see below) been tested.

Medical devices

- Medical electrical equipment EN 60601
- Electromagnetic disturbances - EN 55011:2009
- Radiated Emission EN 61000
- Radiated Immunity EN 61000

The following reports show that the device
passed all tests
- Ref: 17C00309RPT01 DARE Product Safety Test Report
- Ref: 17C00029RPT01 DARE Examination Report
- Ref.: EMC-208-2013 BLUE GUIDE EMC LAB Test Report 20131003
- Ref.: EMC-041-2017 BLUE GUIDE EMC LAB Test Report 20140424

Literature references:

[1] ISO 14155:2011 Clinical investigation of medical devices for
human subjects * Good
clinical practice.

[2] Richtlijn 93/42/EEG van 14 juni 1993 betreffende medische
hulpmiddelen, gewijzigd bij Richtlijn 2007/47/EG van het Europees
Parlement en de Raad van 5 september 2007.

[3] Richtlijn 90/385/EEG van 20 juni 1990 betreffende de onderlinge
aanpassing van de wetgevingen van de lidstaten inzake actieve
implanteerbare medische hulpmiddelen, gewijzigd bij Richtlijn 2007/47/EG
van het Europees Parlement en de Raad van 5 september
2007.

[4] GHTF/SG1/N011:2008 Summary technical documentation for demonstrating
conformity
to the essential principles of safety and performance of medical
devices (STED).

[5] NEN EN ISO 13485:2003 Medische hulpmiddelen *
Kwaliteitsmanagementsystemen *
Bijzondere eisen voor regulering doeleinden.

[6] NEN EN ISO 14971:2009 Medische hulpmiddelen * Toepassing van
risicomanagement voor medische hulpmiddelen (corrected and reprinted).

[7] NEN EN ISO 11135-series over Sterilisatie van producten voor de
gezondheidszorg * Ethyleenoxide.

[8] NEN EN ISO 17665-series over Sterilisatie van producten voor de
gezondheidszorg *
Stoom.

[9] GHTF/SG5/N2R8:2007 Clinical evaluation.

[10] European Commission, Medical Devices: Guidelines on medical devices * Clinical
evaluation: A guide for manufacturers and notified bodies, MEDDEV 2.7.1 rev 3 (December
2009).

Contacts

Public
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
's Hertogenbosch 5223 GZ
NL
Scientific
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
's Hertogenbosch 5223 GZ
NL

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 6 weeks old):
- age older than 18 years
- venous ulcers

- arterial leg ulcers
- ulcers of the lower limbs with mixed ethiology
- pressure ulcers (grade 2 to 4)
- diabetic foot ulcers
- other difficult to treat wounds

Exclusion criteria

Pregnancy an lactation
Use of other internal electronic device (e.g. pacemaker, internale deflibrillator)
Oncologic wound (eg. ulcerating carcinoma)
Mental disability
Diagnosed skin disease
Fever (above 28,5 grades Celcius)
Active wound infection
Not to be able to adequately fill out questionaire
Under 18 years of age
Wounds with necrotic tissue

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Wound stimulation of chronic wounds with micro current device
Registration:	No

Ethics review

Not approved

Date:	29-06-2018
Application type:	First submission
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	NL65974.028.18