PLASOMA Ultimate Safety and Efficacy Study

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This study is designed to confirm the safety and efficacy of PLASOMA after CE marking:1. in a larger population,2. in a more diverse population, consisting also of non-diabetic wound types, and3. including long-term safety.and to determine the...

Ethical review	Approved WMO
Status	Completed
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON54798

Source
ToetsingOnline

Brief title
PULSE study

Condition

- Diabetic complications
- Infections - pathogen unspecified
- Skin and subcutaneous tissue disorders NEC

Synonym
chronic wound - wound infection

Research involving
Human

Sponsors and support

Primary sponsor: Plasmacure
Source(s) of monetary or material Support: Plasmacure

Intervention

Keyword: bacterial load, chronic wounds, cold plasma, safety

Outcome measures

Primary outcome

Primary objectives/outcomes of this study:

1. To evaluate the safety of the PLASOMA by analysing the number and type of device related SAEs, including long term (12 months) follow up.

2. To evaluate* the efficacy of the PLASOMA by measuring the reduction in number of Staphylococcus aureus colonies. This will be done during the frist treatment only.

3. To evaluate* the efficacy of the PLASOMA by measuring the % wound surface area reduction after 12 weeks of treatment.

*) This will be done by comparing the treatment group with the control group.

Secondary outcome

Secondary objectives/outcomes of this study:

1. To evaluate* the safety of the PLASOMA by comparing the number and type of all (serious) adverse events ((S)AEs) in the treatment group with those in the control group, including long term (12 monhts) follow up.

2. To evaluate* the safety of the PLASOMA by assessing (until FU2)

a. % Wound surface area reduction

b. Wound appearance

3. To evaluate* the efficacy of the PLASOMA by measuring the bacterial load reduction. This will be done during the first treatment only:

a. Pseudomonas aeruginosa

b. Total bacterial load

4. To evaluate* the efficacy of the PLASOMA by measuring the wound healing:

a. % Wound healing after 4 weeks of treatment

b. % Wound healing after 12 weeks of treatment

c. Time to healing (until 12 weeks)

d. % Wounds with wound surface area reduction >=50% after 4 weeks of treatment

e. % Wound surface area reduction after 4 weeks of treatment

f. % Wound volume reduction after 4 weeks of treatment

g. % Wound volume reduction after 12 weeks of treatment

5. To evaluate* the efficacy of the PLASOMA by assessing

a. Number of recurrences

b. Quality of life

c. Wound pain

d. Wound infection

6. Health Technology Assessment

7. Patient acceptability of PLASOMA treatment

*) This will be done by comparing the treatment group with the control group.

Study description

Background summary

Safety and efficacy (beneficial effect on bacterial load) of PLASOMA has been demonstrated in a one-armed clinical study on 20 patients with diabetic foot

ulcers with a follow-up period of 3 months. Diabetic foot ulcers are reasoned to be representative for other types of slow-healing and non-healing wounds (included in the intended use) regarding reduction of bacterial load and safety of PLASOMA.

Study objective

This study is designed to confirm the safety and efficacy of PLASOMA after CE marking:
1. in a larger population,
2. in a more diverse population, consisting also of non-diabetic wound types, and
3. including long-term safety.
and to determine the effect of PLASOMA on wound surface area.

Study design

This Clinical Investigation will be a two-armed randomized controlled trial, performed at at least three sites (multi-center) in the Netherlands, in 100 subjects.

The two arms are:
1. Control group: Standard care for 12 weeks or until healing, whichever occurs first;
2. Treatment group: Standard care + PLASOMA treatment for 12 weeks or until healing, whichever occurs first.

Subjects will be allocated to one of the two arms according to a pre-defined randomization schedule and data analysis will be done blinded.

Intervention

After cleaning the wound, a (para)medical professional applies a PLASOMA treatment of two minutes.

The PLASOMA treatment takes maximum 12 weeks with a treatment frequency of maximum once per day and a mimimum of once per week.

Study burden and risks

Subjects will be treated with cold plasma for 2 minutes. The treatment period lasts a maximum of 12 weeks, with a treatment frequency of maximum once per day and a minimum of once per week. After the treatment period, always 3 more appointments follow:
1. 2 weeks after end treatment period
2. 12 weeks after end treatment period, and

3. 12 months after start treatment period (by telephone).
On top of this the following additional contact moments can be needed:
A. When the wound is healed within the treatment period, subject will be contacted twice by telephone to see if the wound did not re-open. This will be done at 5 and 9 weeks after the end of the treatment period..
B. When the wound is not healed within the treatment period, but is healed within 12 months after start of the treatment period, subject will be asked to visit the health institute when the wound is healed and two weeks after healing.

At the start of the study, questions about the current medical situation and medical history will be asked. Subjects are asked to fill in three questionnaires (at the start of the study and after the treatment period). Furthermore, two wound swabs will be taken at the start of the treatment period.

Risks include mild, local and transient sensations during or shortly after treatment. Very commonly tingling, warmth or other mild sensations are felt; slight pain can also be felt.

PLASOMA treatment can possibly improve the treatment of chronic wound, this could reduce complications in the future (like amputations). Risks for the participating subjects are limited and comparable interventions have been shown in previous studies to be safe. That is why we believe it is justified to investigate the safety and efficacy of PLASOMA in subjects with chronic wounds.

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

INCL1: have a slow-healing or non-healing ulcer consisting of, but not limited to diabetic ulcers, venous ulcers, pressure ulcers, burn wounds, skin grafts and flaps and infected post-surgical ulcers.
Standard wound care has not resulted in sufficient healing after at least two weeks (including first line care).
Note: There is no upper limit for the duration that the wound exists. In case a subject has multiple wounds that meet the in- and exclusion criteria, the wound with the longest duration will be chosen for the study.
INCL2: have a wound with a minimum wound surface area of 0.5 cm2 and a maximum diameter of 4.5 cm (~16 cm2 wound surface area for circular wounds).
INCL3: have a minimum age of 18 years old.
INCL4: for home care treatments only: have a grounded wall socket available for connection of PLASOMA.

Exclusion criteria

EXCL1: the subject has one or more of the following contraindications for PLASOMA:
• the wound is very exudative, i.e. wounds in which moisture is visible again within a few minutes after patting dry.
• any implanted active electronic device, such as a pacemaker, is present.
• an electronic medical device is attached to the body, including electronic life support equipment, hearing aids, glucose sensors and insulin pumps. If the sole purpose of the medical device is monitoring, the subject is not excluded, but it should be noted that use of PLASOMA together with such devices has not been tested and may lead to erroneous operation of the attached device during PLASOMA treatment.
Note: no exclusion if electronic medical device will be detached during PLASOMA treatment.
• a metal implant (including a stent) is present in the treatment area, i.e. the area between pad and electrode.

• a conductive connection from outside to inside the body at or near the heart is present, e.g. a catheter with electrolyte fluid.
• the subject has epilepsy
• the subject is pregnant
• the to-be-treated wound is located on the torso above the navel
EXCL2: the subject has any known malignant wound degeneration.
EXCL3: the subject receives treatment with immunosuppressive agents or oral corticosteroids; no exclusion if subject has received a stable dose for at least 2 months and the oral corticosteroid dose does not exceed 7.5 mg/day prednisone or equivalent.
EXCL4: the subject is receiving or likely to receive advanced wound therapies - such as negative pressure therapy, hyperbaric oxygen therapy, biologicals (e.g. skin substitutes, growth factors), electrophysical therapy - until FU1 for the to be-treated wound. Advanced wound dressings are not excluded.
EXCL5: the subject participates in another study which is likely to compromise the outcome of the PULSE study or the feasibility of the subject fulfilling the PULSE study.
EXCL6: the subject is unable to provide consent.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-05-2021
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	PLASOMA
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	17-01-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-02-2022
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-04-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	01-11-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-11-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-09-2023
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL71243.015.22