PLASOMA Efficacy & Technology Health study.
A post-market randomised controlled efficacy study of PLASOMA on wound healing in chronic venous leg ulcers.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON54101

Source
ToetsingOnline

Brief title
PETH study

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Skin and subcutaneous tissue disorders NEC

Synonym
chronic wound - venous leg ulcer

Research involving
Human

Sponsors and support

Primary sponsor: Plasmacure B.V.
Source(s) of monetary or material Support: Horizon2020 (Europese Commissie)

Intervention

Keyword: chronic wounds, cold plasma, venous leg ulcers, wound healing

Outcome measures

Primary outcome

Evaluate the percentage of wounds healed after 12 weeks of treatment with

PLASOMA for two treatment frequencies: once per week and twice per week.

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

Secondary outcome

Evaluate the effect and safety of PLASOMA by assessing:

• % Wound healing after 4 weeks

• Time to healing (until 12 weeks)

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

• % Wound surface area reduction after 4 and 12 weeks of treatment

• % Wound volume reduction after 4 and 12 weeks of treatment

• Number of recurrences at 5, 9 and 12 weeks after end treatment period

• Scarring at FU1 and FU2

• Quality of life: RAND-36 (general) and Wound-QOL (wound specific)

• Wound pain during treatment period

• Wound infection

• Resources involved (input for Health Technology Assessment)

• Patient acceptability during treatment period

• Adverse Events with a potential relation to PLASOMA

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

Study description

Background summary

Safety and efficacy (positive effect on bacterial load) of PLASOMA has previously been demonstrated on 20 patients with diabetic foot wounds, in a 1-arm clinical trial with a follow-up period of 3 months.

This post market study is a follow-up to a previous clinical study on diabetic foot wounds used to obtain CE marking and an addition to another post market study that aims to confirm safety and efficacy in a larger and more diverse population (50% diabetic foot wounds, 50% other chronic wounds) with long-term safety monitoring. The aim of this post market study is to investigate the efficacy of PLASOMA on wound healing in a group of patients with venous leg ulcers (VLUs).

Study objective

This study is designed to examine beneficial effects of PLASOMA treatment compared to the standard of care on chronic venous leg ulcers (VLU) that match the size of the plasma area of the pad.

The intention is that the data obtained with this study will be used to:
1. Demonstrate comparative performance of PLASOMA (for two treatment frequencies)
2. Provide evidence for health technology assessments (HTA) of PLASOMA

Study design

The PETH study will be an open label three-armed randomized controlled trial (RCT) on chronic VLU. The study will be performed at one study site in the Netherlands.

The three arms are:
• Control group: standard care for 12 weeks or until healing, whichever occurs first;
• Treatment group-1: standard care + PLASOMA treatment once per week for 12 weeks or until healing, whichever occurs first;
• Treatment group-2: standard care + PLASOMA treatment twice per week for 12 weeks or until healing, whichever occurs first.

After the treatment period there will be two follow up timepoints: 2 weeks after the end of the treatment period (FU1) and 12 weeks after the end of the treatment period (FU2).

Subjects will be allocated to one of the three arms according to a pre-defined randomization schedule.

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 once per week for the first two arms and a frequency of twice per week for the third arm (treatment group-2).

Study burden and risks

Subjects will be treated with cold plasma for 2 minutes. The treatment takes maximum 12 weeks with a treatment frequency of once per week or twice per week (depending on the study arm). After the treatment period there are two follow up moments: 2 and 12 weeks after the end of the treatment. On top of this the following additional contact moments can be needed:
A. When the wound is healed within the treatment period, the 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 weeks after the end of the treatment period, a (home) visit will take place 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).

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. 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 lower leg ulcer presumed to be caused by venous insufficiency (VLU). The wound should have insufficient healing (<30% surface area reduction) during the last 2 weeks of standard wound care.
INCL2: have a wound with a minimum wound surface area of 0.5 cm2 and

a maximum diameter of 6 cm (~28 cm2 wound surface area for circular wounds).
INCL3: have an Ankle Brachial Pressure Index (ABPI) between 0.8 and 1.3.
Note 1: subject can be included based on a VLU diagnosis from anamnesis. Make sure an ABPI measurement is performed as soon as possible to verify the diagnosis. The subject has to be excluded if the ABPI is not between 0.8 and 1.3.
Note 2: For diabetic patients an ABPI measurement is not always reliable. Therefore, diabetic patients can be included based on a VLU diagnosis from anamnesis, but no ABPI measurement needs to be performed.
INCL4: have a minimum age of 18 years old.
INCL5: For home care treatments only: there is 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
EXCL2: the subject uses systemic antibiotics.
EXCL3: the subject has any known malignant wound degeneration.
EXCL4: 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.
EXCL5: the subject is receiving or likely to receive advanced wound dressings or advanced therapies- such as negative pressure therapy,

hyperbaric oxygen therapy, biologicals (e.g. skin substitutes, growth factors), electrophysical therapy - for the to-be-treated wound.
EXCL6: the subject cannot (agree to) comply with the SOC.
EXCL7: the subject participates in another study which is likely to compromise the outcome of the PETH study or the feasibility of the subject fulfilling the PETH study.
EXCL8: 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:	Recruitment stopped
Start date (anticipated):	12-07-2021
Enrollment:	150
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	25-05-2021
Application type:	First submission

Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	11-01-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
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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	NL76826.015.22