Safety assessment of cold gas plasma on intact skin

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Primary objective1. To test the safety of cold plasma treatment: SAE in * 10% of participants, no pain (VAT * 2) and no local skin reaction: redness, blister formation, pain or itching. Secondary objectives:The effect of cold plasma treatment on : 1...

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

Summary

ID

NL-OMON47073

Source
ToetsingOnline

Brief title
Cold plasma on skin

Condition

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

Synonym
burn wound infection, wound contamination

Research involving
Human

Sponsors and support

Primary sponsor: Vereniging Samenwerkende Brandwondencentra Nederland
Source(s) of monetary or material Support: zonMw

Intervention

Keyword: Gas Plasma, Pain, Safety, Skin

Outcome measures

Primary outcome

Safety of plasma treatment: occurance of SAE and pain scores will be recorded.

Plasma treatment is considere safe when in * 10% moderate SAE due to the

treatment.

Pain: a VAT score above 2 is considered as a cutoff value for SAE.

Secondary outcome

The effect of plasma treatment on TEWL, local skin temperature, colorimetry and

bacterial load will be determined.

Study description

Background summary

Burn patients are at risk of wound colonization or infection because of reduced immune responses and a large exposed surface area. The presence of micro-organisms in (burn) wounds can have a serious impact on wound healing and can result in complications and a longer length of stay. Antimicrobial treatments with crèmes are not sufficient and can even be detrimental to wound healing. Since bacterial (multi)drug resistance continues to increase steadily, use of (systemic) antibiotics is limited.
Cold gas plasma can offer a new alternative to combat bacteria in (burn)wounds. Cold gas plasma can be created by discharging gas at roomtemperature, at normal atmospheric pressure. Contact of plasma with ambient air results in the creation of active particles such as oxygen and nitrogen radicals. Production of these particles can be adjusted to a safe level. Plasma has the ability to kill high numbers of bacteria in minutes whitout causing damage to skin cells and is therefor a powerful method to prevent and treat infections.

Study objective

Primary objective

1. To test the safety of cold plasma treatment: SAE in * 10% of participants, no pain (VAT * 2) and no local skin reaction: redness, blister formation, pain or itching.

Secondary objectives:
The effect of cold plasma treatment on :
1. skin characteristics: colour/pigmentation, temperature, barrière function (TEWL)
2. killing of bacteria on intact skin

Study design

1. Tests for safety and absence of pain on 10 volunteers.

2. Determine the effect of plasma on bacterial survival on skin of 15 volunteers. Safety aspects are included as well.

Intervention

Volunteers will be treated once with cold gas plasma.

Study burden and risks

Expected risks include skin sensations (pain, paresthia, warmth), which in previous studies ranged from none to mild symptoms that were deemed acceptable by the subjects.

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

-18 years or older,
-have completed informed consent forms;
-able and willing to comply with the research protocol;
-no language barrier

Exclusion criteria

- Atopic dermatitis or other skin disease
- Implanted electrical medical devices such cardiac pacemakers
- Pregnant or lactating women
- Patients with infected wounds.
- Life-threatening cardiac conductivity abnormality
- Active malignancy
- Women of childbearing age not using contraceptive measures

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-06-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Cold atmospheric gas plasma device
Registration:	No

Ethics review

Approved WMO Date:	29-05-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL52211.094.16