# Treatment of diabetic foot wounds with cold plasma plaster.

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22100

**Source**
NTR

**Brief title**
Cold Plasma in Diabetic Foot Ulcers.

**Health condition**

Plasma Gases
Adult
Diabetic foot
Ulcer

Diabetische voet
Ulcus
Plasma pleister
Volwassenen

### Sponsors and support

**Primary sponsor:** VU University Medical Center.
**Source(s) of monetary or material Support:** Diabetes Fonds Nederland.

### Intervention

## Outcome measures

### Primary outcome

Safety of CAP treatment in diabetic foot ulcers. CAP treatment is considered safe when in ≤ 10% serious adverse advents other than infection occur, and if ≤ 60% of patients have infection.

### Secondary outcome

• The effect of CAP treatment on bacterial load is considered clinically significant if bacterial load is reduced with 50% at day 14 compared to day 1 as measured by deep tissue swab, and 50% reduction in bacterial load before and directly after cold plasma plaster treatment on day 1, 7 and 14.

• Healing of the wound, defined as full epithelialization, at 2 and 12 weeks after start of treatment.

• Occurrence of clinically defined infection according to the International Working Group on the Diabetic Foot/Infectious Diseases Society of America's classification [15,16] during treatment and after treatment.

• Clinical outcome (amputation, death, wound healing, treatment with antibiotics) 3 months after enrolment.

• Quality of life 3 months after enrolment measured with questionnaires (PAID-NL, SF-36, USER-P).

# Study description

### Background summary

Plasma medicine is an innovative field of research with a high potential but with little clinical evidence to its support. Cold atmospheric plasma (CAP) devices generate an ionized gas with a cocktail of highly reactive species and UV light. They can be used for application on living tissue because these operate at normal ambient air pressure and temperature[1][2][3]. CAP treatment has advantages over antiseptic or antimicrobial infection prevention and control, e.g. efficient, painless, instant disinfection without chance of developing antimicrobial resistance, but with stimulation of fibroblast proliferation and migration contributing to wound healing. Current evidence for CAP consists of in-vitro studies, animal studies, and studies in patient groups such as those with burn wounds. Our novel type of CAP device[4] is simple to use and can be applied by a podiatrist and even at a patient's home. This is a pilot study to safety and efficacy of the technology.

### Study objective

We hypothesise that CAP is a safe treatment that reduces bacterial load on the wound surface and promotes wound healing.

### Study design

1-7-2015 inclusion patients 1-10.

1-11-2015 intermediate evaluation.

1-12-2015 inclusion patients 11-20.

1-4-2016 evaluation.

### Intervention

20 patients with foot ulcers will be treated on an outpatient basis with daily CAP for 10 days in 2 weeks. Bacterial load will be measured by culture and molecular technique of deep tissue swab at days 1, 7 and 14, and directly before and after CAP application. Standard protocols for wound treatment will be deployed, including proper offloading.

## Contacts

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# Eligibility criteria

## Inclusion criteria

- Type 1 or 2 diabetes mellitus

- Foot ulcer with a maximum depth of 5 millimeters, with or without peripheral vascular disease, without evidence of bone or joint tissue in the wound base, without overt clinical infection (University of Texas Wound Classification A1, A2, C1 or C2) [17]

- Able and willing to comply with the research protocol.

## Exclusion criteria

- Implanted electrical medical devices such cardiac pacemakers

- Life-threatening cardiac conductivity abnormality

- Active malignancy

- Pregnant or lactating women

- Women of childbearing age not using contraceptive measures

- A foot infection needing antibiotic treatment

- Patients with deep wounds (> 5 millimeters) or with bone or joint tissue in the wound base.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Factorial |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-04-2016 |
| Enrollment: | 20 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

## 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 |
|---|---|
| NTR-new | NL4968 |
| NTR-old | NTR5090 |
| Other | 2001440 : VU University Medical Center |

## Study results