# Pecan Study:
# Pilot and explorative study comparing the effects of a capillary dressing to negative pressure wound therapy

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON55085

**Source**
ToetsingOnline

**Brief title**
PECAN

### Condition

- Other condition

**Synonym**
postoperatively wounds, wounds after surgery

**Health condition**

postoperatieve wonden (dehiscenties en/of infecties)

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** capillairy dressing, negative pressure therapy, pilot study, standard wound care

## Outcome measures

### Primary outcome

Feasability outcomes

- participants* acceptability of the research plan

- recruitment and attrition rates

- effect size to facilitate sample size calculations for the definitive study

Outcomes of effect:

The primary outcome is time to complete wound healing.

### Secondary outcome

Secondary outcomes are:

* Time to granulation up to level of the skin

* Quality of Life (QoL)

* Experienced pain (during dressing changes and in between dressing changes)

* Experienced itch

* Number of adverse and serious adverse events

* Direct costs of treatment (i.e. costs of the dressings used, per person)

# Study description

### Background summary

With an incidence of 1.5 * 20 % in European countries, surgical site infections (SSI) are a frequent problem leading to significant wound dehiscences, morbidity and mortality. Despite the lack of adequately powered RCTs, in many clinics Negative Pressure Wound Therapy (NPWT) is the first choice of treatment on surgical wounds healing by second intention. Thereby, the success of NPWT is not only determined by its efficacy, but also by its impact on the patients* quality of life (QoL). It is suggested that a new available capillary dressing is a valuable alternative to NPWT in terms of better tolerance by the patient with wounds healing by secondary intention due to SSI and comparable time to achieve complete wound healing. Up to now, studies have mainly compared the effectiveness of NPWT with Standard Wound Care (SWC; i.e. no capillary dressing). Therefore, we propose conducting this pilot study to compare time to complete wound healing and experienced QoL between NPWT and a capillary dressing and with SWC. We aim to establish the feasibility of conducting a definitive randomised controlled trial (RCT) comparing the effectiveness of this capillary dressing with NPWT and with SWC.

### Study objective

Therefore, we propose conducting this pilot study to compare time to complete wound healing and experienced QoL between NPWT and a capillary dressing and with SWC. We aim to establish the feasibility of conducting a definitive randomised controlled trial (RCT) comparing the effectiveness of this capillary dressing with NPWT and with SWC.

### Study design

A multicenter, randomized pilot study. Patients will be randomized to one of the three treatment arms: (1) a capillary dressing (Vacutex* ); (2) NPWT; and (3) SWC.

### Intervention

A capillary dressing (i.e., Vacutex*) will be compared with a commercially available NPWT and standard wound care (defined as dressings providing a moist wound environment which are routinely used in the participating hospital site).

### Study burden and risks

Participants will be asked to fill in an EQ-5D-5L questionnaire at baseline (day of inclusion), after one week and when the wound has healed,

taking up 15 minutes in total. Furthermore, patients will be asked to take photos (or let the (home care) nurse take photos) of their wound at baseline, when granulation tissue has reached skin level and when complete wound healing has been achieved. Additionally, patients will be asked to score on a Visual Analogue Scale (VAS) the experienced pain and itch, daily and during dressing changes.
NPWT and capillary dressings are both commonly used wound treatments nowadays. Although many patients have benefited from NPWT, adverse events*including deaths and serious injuries*have been reported to the FDA.[1] The most serious adverse events associated with NPWT, blood loss and infection, can be prevented if healthcare professionals pay close attention to criteria for patient selection, instructions for use and appropriate care setting.[1] Nevertheless, NPWT has been shown to be a safe intervention in several systematic reviews, where the risks described above were not designated to be a problem. No adverse events of Vacutex* are described.

## 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
* Informed consent
* having a postoperatively infected wound and/or a wound dehiscence (> 1 cm in depth)

### Exclusion criteria

* allergy to one or more of the components of the capillary dressing
* exposed vessels
* malignant cells in wound
* heavily bleeding wounds
* if NPWT or Vacutex* is not a treatment option
* not familiar with the Dutch language (able to read the informed consent form and to fill in the EQ-5D-5L questionnaire)

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-08-2020 |
| Enrollment: | 75 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Negative Pressure wound therapy |
| Registration: | Yes - CE intended use |

## Ethics review

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| Approved WMO Date: | 19-05-2020 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 08-09-2020 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 03-05-2021 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | NL72850.091.20 |

## Study results

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|---|---|
| Date completed: | 20-10-2021 |
| Actual enrolment: | 7 |