Comparing Negative Pressure Wound Therapy with Instillation vs. Standard wound care to treat postoperative wound infections

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19878

Source
NTR

Brief title
SCONE

Health condition

SSI, POWI

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Time to complete wound healing, defined as re-epithelization of the total wound surface or if

the wound is ready for secondary surgical closure (i.e., healthy red granulation tissue without signs of infection or debris).

Secondary outcome

• pain (using a Numeric Rating Scale (NRS) scored for the first two weeks daily; and during dressing changes for the first four weeks);
• hospital length of stay (HLOS);
• hospital readmissions (wound-related) (within 30 and 90 days after discharge);
• frequency and type of surgical procedures related to SSI within 30 and 90 days after start treatment;
• health-related quality of life (using the EQ-5D-5L) at baseline; and after 30 & 90 days, 6 and 12 months after inclusion);
• patient satisfaction (Numeric Rating Scale (NRS) ranging from 0-10 score);
• duration of total wound care, frequency of wound care (e.g., dressing changes) (during admission);
• the need for homecare (and duration) for wound care after discharge from hospital;
• costs (mean material costs per day; mean costs nursing time per dressing change based Dutch tariff; iMTA Medical Consumption Questionnaire (iMCQ); the iMTA Productivity Cost Questionnaire (iPCQ) at baseline and after 30 & 90 days, 6 and 12 months after inclusion;
• professional satisfaction (Numeric Rating Scale (NRS) ranging from 0-10 score).

Study description

Background summary

Rationale: Surgical wounds are the most common wounds seen in daily clinical practice and are associated with a variety of complications such as bleeding and dehiscence. Surgical site infections (SSI) are the most common complication, and the high rates of POWI leads to additional treatment, prolonged hospital stay, patient discomfort, and as a result of this a substantial increase in costs. Negative Pressure Wound Therapy with Instillation (NPWTi) use is growing as a therapeutic approach to treat postoperative wound infections (POWIs), yet high quality evidence of its effectiveness is lacking. Our hypothesis is that time to complete wound healing in patients with a POWI who receive NPWTi will be shorter than in patients receiving standard wound care (i.e., NPWT and/or conventional wound care).
Objective: To investigate if the use of initial NPWTi leads to a faster wound healing compared to standard wound care only in patients with a POWI.
Study design: An investigator-initiated multicentre randomized controlled trial. Patients will be randomized to NPWTi or standard wound care with a 1:1 ratio. An a priori power analysis and an anticipated dropout rate of 10% indicates that 223 patients per group are needed, totalling 446 patients to be able to detect a 14-day reduction in wound healing time.
Study population: All patients (≥18 years) who have a POWI plus a wound dehiscence (> 5 cm dehiscence) will be eligible, as well as patients with a wound that needs to be opened for drainage of POWI. The wound should have a minimum size of 10 cm² to allow proper

application, and should be suitable for all treatment options in the trial. Patients are included after giving written informed consent.
Intervention: NPWTi (after debridement if needed). The wound will be covered with an open-cell foam and an occlusive drape. During repeated cycles, the wound bed will be automatically soaked with 0.9% normal saline for 15 minutes followed by negative pressure cycle at -125 mmHg for 2,5 hours; cycle length depending on the bioburden of the wound. The foam and drape are changed every 2-3 days (1 treatment period). At least two treatment periods of 2-3 days need to be completed before switch to standard NPWT (preferred) or conventional dressing.
Comparison/usual care: Standard wound care (after debridement if needed). This involves the use of NPWT and/or conventional dressings, depending on local standards. NPWT involves open-cell foam and occlusive drape with negative pressure treatment but without intermittent topical delivery of instillation fluid and soaking cycles. Conventional dressings are gauze-based or occlusive dressings and will be used until the wound is completely healed.
Main study parameters/endpoints: Primary outcome: Time to complete wound healing defined as re-epithelization of the total wound surface or if the wound is ready for secondary surgical closure (i.e. healthy red granulation tissue without signs of infection or debris). Secondary outcomes: pain (NRS), length of stay, readmissions for wound related complications, frequency and type of surgical procedures related to SSI within 90 days, quality of life, patient-and professional satisfaction, duration of total wound care, frequency of wound care (e.g., dressing changes), the need for homecare for wound care after discharge from hospital, and costs. Additionally, three planned subgroup analysis of wound healing will be performed: (1) NPWT vs. conventional wound care within the standard care group; and (2) wound healing after secondary surgical closure vs. no secondary surgical closure; (3) foreign body-associated infections from implants of index operation vs. no foreign body-associated infections from implants of index operation.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be asked to report pain scores (using a Numeric Rating Scale (NRS) scored for the first two weeks daily, and during dressing changes for the first four weeks) (in total: approximately 30 minutes). They will be also be asked to complete the EQ-5D-5L health status questionnaire, the iMTA Medical Consumption Questionnaire (iMCQ) and the iMTA Productivity Cost Questionnaire (iPCQ) at baseline, and after 30 & 90 days, 6 and 12 months after inclusion) (approximately 20 minutes per measurement), and to take photos of their wound at baseline, and after 30 & 90 days, 6 and 12 months after inclusion) and during dressing changes (approximately 5 minutes per measurement). NPWTi, NPWT and conventional wound care are all used as a therapeutic aid to treat POWIs, and are considered as safe interventions.

Study objective

Our hypothesis is that time to complete wound healing in patients with a POWI who receive NPWTi will be shorter than in patients receiving standard wound care (i.e., NPWT and/or conventional wound care). We do not expect that NPWTi pose an extra risk to the patients, and published data (RCTs and observational studies) have shown no such risk.

Study design

• Baseline
• First 28 days after start treatment
• +30 days / +90 days / +6 months/ +12 months after start treatment
• At discharge, +30 days/ +90 days after discharge

Intervention

NPWTi (intervention), NPWT and/or conventional wound care (control)

Contacts

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Eligibility criteria

Inclusion criteria

• Age equal or older than 18 years;
• A superficial or deep surgical site infection plus a wound dehiscence (> 5 cm dehiscence) or a wound that needs to be opened for drainage of surgical site infection after any type of surgery;
• Surgical site infeciton occurring within 30 days after surgery;
• A minimum wound size of 10 cm^2 to allow proper application of the study treatments;
• Written informed consent.

Exclusion criteria

• A deep organ/space surgical site infection without a superficial (involvement of skin and

fascia) wound infection
• Psychically or mentally inability for informed consent
• Fascial dehiscence > 0,5 cm
• Malignancy in the wound
• Untreated osteomyelitis
• Enteric fistula
• The wound located where there is a risk of unintented fluid delivery to the thoracic or abdominal cavity.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	446
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-08-2021
Application type:	First submission

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	NL9675
Other	METC AMC : METC2021_082

Study results