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

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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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON54383

Source
ToetsingOnline

Brief title
SCONE: Standard Wound care Compared to NPWTi Effectiveness

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
inflammation, wound infection

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Zonmw

Intervention

Keyword: Negative-Pressure Wound Therapy, Randomized Controlled Trial, Surgical wound infection, Wounds and Injuries

Outcome measures

Primary outcome

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

Secondary outcomes:

• 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 90 days

post-operative;

• 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).

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.

Study description

Background summary

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 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).

Study 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.

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 2-3 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: 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.

Study burden and risks

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.

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

In order to participate in this study, a subject must meet all of the following criteria:
• Age equal or older than 18 years;
• A superficial or deep SSI plus a wound dehiscence (> 5 cm dehiscence) or a wound that needs to be opened for drainage of SSI after any type of surgery;
• SSI 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 potential subject who meets any of the following criteria will be excluded from participation in this study:
• A deep organ/space SSI without a superficial (involvement of skin and fascia) wound infection
• Psychically or mentally inability for informed consent
• Fascial dehiscence > 0,5 cm

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2021
Enrollment:	446
Type:	Actual

Medical products/devices used

Generic name:	Veraflo negative pressure wound therapy with instillation system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-07-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL76838.018.21