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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19878

Bron
NTR

Verkorte titel
SCONE

Aandoening

SSI, POWI

Ondersteuning

Primaire sponsor: ZONMW
Overige ondersteuning: ZONMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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 cm^2 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.

Doel van het onderzoek

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.

Onderzoeksopzet

• 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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	446
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-08-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9675
Ander register	METC AMC : METC2021_082

Resultaten