Validation of Manual Negative Pressure Wound Therapy for Open Wounds

Gepubliceerd: 21-09-2021 Laatst bijgewerkt: 18-08-2022

Manual negative pressure wound therapy is safe and is more effective than standard gauze dressing, in terms of duration of treatment and number of wound dressings.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25554

Bron
NTR

Verkorte titel
PragmaVAC

Aandoening

Acute and chronic open wounds

Ondersteuning

Primaire sponsor: Pragmatic Innovation Inc, Mississauga, ON, Canada
Overige ondersteuning: The Ministry of Foreign Affairs of the Netherlands, UKAID, and the Canadian Government via Humanitarian Grand Challenge, a program of Grand Challenges Canada

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of dressings and duration in days required for the wound to become ready for

closure, defined by nourished wound bed with good granulation tissue.

N.B. The final wound closure (by suturing, split-thickness skin graft, or secondary intention) is outside the scope of the trial.

Toelichting onderzoek

Achtergrond van het onderzoek

Negative pressure wound therapy (NPWT) is an established and widely used treatment for open wounds including acute and chronic wounds, such as traumatic wounds, pressure ulcers, diabetic foot ulcers and post-operative wounds. It is known to markedly accelerate wound healing and prevent infectious complications, with favorable patient outcomes.

The mechanism of action of NPWT involves promoting blood flow to the wound, reducing edema and stimulating angiogenesis and granulation tissue formation. It also causes mechanical stress in the bed of the wound, thus promoting cell proliferation. The recommended negative pressure levels range from -80 to -120 mmHg, which is what is used in the clinical practice.
Potential side effects are pain, mainly associated with dressing changes, and bleeding which is predominantly minor bleeding from granulation tissue.

The purpose of this study is to validate the safety and efficacy of a manually operated negative pressure wound therapy device (PragmaVAC) compared to the standard gauze dressing in a controlled non-blinded open label clinical trial. PragmaVAC is activated by manual pumping by the patient or their caregiver, when needed. Exudate fluid is collected in a built-in canister that can be detached and cleaned by the patient or their caregiver. The study will focus on resource constrained environments.

Doel van het onderzoek

Manual negative pressure wound therapy is safe and is more effective than standard gauze dressing, in terms of duration of treatment and number of wound dressings.

Onderzoeksopzet

On day 1, the patient’s wound will be assigned to the study arm and receive the corresponding treatment (gauze or NPWT). Baseline data will be collected in the first visit. Patients will visit the health facility for wound care and dressing change. During each visit the wound data and photos will be collected for wound status assessment. The final data collection will take place on the day when the wound reaches the primary outcome.

Onderzoeksproduct en/of interventie

Wounds in the intervention group will be covered with standard NPWT dressing, consisting of specialized foam covering the wound pad, and then sealed with an air-tight drapes. A tube extends from the foam to be connected to the device. The NPWT dressing components (i.e. the foam, drapes, and tube) come in standard off-the-shelf package, which is not part of the validation on its own.
PragmaVAC manual negative pressure device is then connected to the dressing tube. The device generates the recommended negative pressure, by means of manual pumping. The patient can continue their treatment in the home while using the manual device as instructed by their physician.

Wounds in the control group will be treated with conventional gauze-based wound therapy, which is the standard of care for wound dressing.

Patients in both groups will visit the health facility every few days. In each visit, wound status and metrics will be assessed, in terms of infection and granulation tissue formation. Additionally, wound photos will be taken for digital area measurement.

In case of multiple wounds in the same patient, each wound is assigned as a single case.

Contactpersonen

Publiek

Pragmatic Innovation Inc
Hisham Alshaer

+14168234717

Wetenschappelijk

Pragmatic Innovation Inc
Hisham Alshaer

+14168234717

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

We will recruit patients ≥ 18 years of age with these criteria:

1- Patients with a full-thickness wounds that could not be closed immediately.
2- Infected and non-infected wounds
3- Acute and chronic wounds; the latter include pressure ulcers and diabetic foot wounds
4- Body areas where wound dressing plaster can be sealed (air-tight)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1- Wounds that are considered ready for primary closure by suturing or skin graft.
2- History of psychiatric disorders that can affect patient's insight or judgement, namely, schizophrenia and other psychotic disorder, bipolar disorders, dementia, and intellectual disabilities, as assessed by the treating physician.
3- Body areas where plaster cannot be sealed (e.g. perineum, body folds, presence of external fixators) or an unstable skin around the wound
4- Standard clinical contraindications to NPWT such as:
- Exposed bone or untreated osteomyelitis
- Superficial bare blood vessels and/or active bleeding
- Deep fistulas in the wound location
- Uncontrolled diabetes
5- Exposed peritoneum
6- Systemic sepsis caused by wound infection. These patients could become eligible once their sepsis is resolved and/or necrotic tissue is debrided.
7- Grossly necrotic wounds
8- Malignancy in the wound

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-03-2021

Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL9751
Ander register	Veritas IRB, Kirkland, Quebec, Canada : 2020-2377-3537-3

Resultaten