Validation of Manual Negative Pressure Wound Therapy for Open Wounds

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25554

Source
NTR

Brief title
PragmaVAC

Health condition

Acute and chronic open wounds

Sponsors and support

Primary sponsor: Pragmatic Innovation Inc, Mississauga, ON, Canada
Source(s) of monetary or material Support: The Ministry of Foreign Affairs of the Netherlands, UKAID, and the Canadian Government via Humanitarian Grand Challenge, a program of Grand Challenges Canada

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- Wound shrinkage measured from day 1 of treatment to primary outcome

- Wound infection observed by clinical signs of infection and purulent discharge

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2021
Enrollment:	70

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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

Study results