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Pilot study designed to assess functionality of a low-cost negative pressure wound therapy system

Submission date
21/05/2018

Recruitment status
No longer recruiting

Registration date
30/05/2018

Overall study status
Completed

Last Edited
30/05/2018

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Healyx Labs is developing a Negative Pressure Wound Therapy device (NPTWD) designed for low-resource medical settings. The Healyx Labs NPWT device is designed to provide a controlled amount of suction (negative pressure) to a wound site through an airtight dressing applied to a patient's wound. Suction removes fluids from the wound and provides wound contraction and tissue changes that can promote wound healing. The aim of this study is to evaluate the feasibility of using the NPWT device in low-resource medical settings.

Who can participate?
Patients over 18 years of age who have a wound that can be treated by the device. These wounds include chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure, or venous insufficiency), flaps, grafts and surgical incisions

What does the study involve?
After wound cleansing and preparation, treatment with the NPWT device begins. The dressing is cut to size and applied. The suction device is attached to the dressing and turned on. The vacuum is left on for up to six weeks, or until the investigator determines that the wound is healed or ready for a further intervention. During this time, caregivers are instructed to check on the treatment daily. Wound dressing changes occur at least twice a week. After completion of the intervention, the patient is contacted four to six weeks later to assess satisfaction with treatment and quality of life.

What are the possible benefits and risks of participating?
Healyx Labs is not claiming to directly benefit participants. Healyx does expect the NPWTD to provide comparable benefits to those of existing negative-pressure wound therapy vacuums, including faster healing. Healyx Labs is not introducing new risks to those listed with standard NPWT devices. Additionally, standard NPWT risk for adverse events is lower than that associated

with makeshift wall and surgical suction devices. All dressings used in the study are certified as sterile and the Healyx device itself provides a pressure of 125 mmHg, considered safe for use in negative pressure wound therapy.

Where is the study run from?
Kirtipur Hospital (Nepal)

When is the study starting and how long is it expected to run for?
November 2017 to May 2018

Who is funding the study?
Healyx Labs (USA)

Who is the main contact?
Cam Hutton

Contact information

Type(s)
Public

Contact name
Mr Cam Hutton

Contact details
2500 Grant Rd G01
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United States of America
94040

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CLN100

Study information

Scientific Title
Pilot study designed to assess functionality of a low-cost negative pressure wound therapy system in patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure, or venous insufficiency), flaps, grafts and surgical incisions

Acronym

Healyx NPWTD Pilot Study

Study objectives
Primary Objectives: To determine NPWT device ease of use in a low-resource setting
Secondary Objectives: To assess safety of device design; to assess healing progression and quality of life for patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Public Health Concern Trust, Nepal (phect-NEPAL) Institutional Review Committee (IRC) , 14/02 /2018, ref: 1824

Study design
Prospective single-arm interventional pilot study in a single site

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure, or venous insufficiency), flaps, grafts and surgical incisions

Interventions
The Healyx Labs NPWT suction unit provides suction at the gold standard level for Negative Pressure Wound Therapy (-125mmHg +/- 10%) from a built-in diaphragm pump powered by a DC motor. The pressure setting at -125 mmHg is the standard pressure used in predicate devices and has application in treatment for majority of wound types. The suction unit has a casing that holds a disposable suction container that collects fluids leaving the patient’s sealed wound bed.

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Intervention Type
Device

Primary outcome measure
Ease of use measured by user reported rankings of device procedures at each dressing change:
1. Users (caregivers) are confident in setting up the device and creating successful suction. Device user completes a device assessment at each dressing change (twice per week) and at device removal measuring:
1.1. Overall satisfaction with a Likert scale
1.2. Usability compared to current wound therapies
2. Users are able to successfully remove the device during dressing changes. Device user completes a device assessment at each dressing change and at device removal measuring:
2.1. Overall satisfaction with a Likert scale
2.2. Usability compared to current wound therapies

Secondary outcome measures
1. Safety of device design evaluated by the incidence and intensity of device-related adverse events (AEs). Patient is interviewed and observed visually for device-related adverse events at treatment initiation and each dressing change
2. Healing progression at six weeks or conclusion of therapy, if earlier
3. Pain measured using a validated pain scale VAS recorded at 1x dressing change per week
4. Quality of life measured using questionnaire modified using the EuroQol Derived Single Index (EQ-DSI) recorded at 1x dressing change per week

Overall study start date
01/11/2017

Completion date
26/05/2018

Eligibility

Key inclusion criteria
1. Patient is 18 years of age or older
2. Patient presents with an open wound
3. Patient is able to understand study requirements, is willing to undergo subject procedures, provide any required subject feedback, and provide informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Up to 15

Key exclusion criteria
1. Patient who is pregnant or nursing
2. Patient with a non-survivable wound, life expectancy of 7 days or less
3. Patient’s wound is of malignant or vasculitis origin, or shows presence of necrotic tissue
4. Patient’s wound has active bleeding, exposed blood vessels or organs
5. Patient with wound-related comorbidities, including diabetic ketoacidosis, Hyperglycaemic Hyperosmolar Nonketotic Coma, vascular disease, or arthritis
6. Patient currently using medications that cause immune suppression
7. Patient with wound considered too difficult to seal based on location
8. Patient unable to understand study or provide informed consent to participate in the study

Date of first enrolment
26/02/2018

Date of final enrolment
18/04/2018

Locations

Countries of recruitment
Nepal

Study participating centre
Kirtipur Hospital
Thapathali-11
Kathmandu
Nepal
44618

Sponsor information

Organisation
Healyx Labs

Sponsor details
El Camino Hospital
Fogarty Institute for Innovation
2500 Grant Rd G01
Mountain View
United States of America
94040

Sponsor type
Industry

Website
healyxlabs.com

Funder(s)

Funder type
Industry

Funder Name
Healyx Labs

Results and Publications

Publication and dissemination plan
The company is not making study documents available as the device does not yet have regulatory approval and the data are confidential and proprietary. The study documents are held at the clinical trial site in Nepal. Planned publication of the results in a peer reviewed journal by May 2019.

Intention to publish date
01/05/2019

Individual participant data (IPD) sharing plan
The company is not making the participant level data available as the device does not yet have regulatory approval and the data are confidential and proprietary. The data are held at the clinical trial site in Nepal.

IPD sharing plan summary
Not expected to be made available