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Does a simple modification of the VAC therapy system reduce the daily treatment cost for wounds?

Submission date
20/08/2018

Recruitment status
No longer recruiting

Registration date
02/01/2020

Overall study status
Completed

Last Edited
17/03/2022

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Acute and chronic wounds are a major healthcare problem. They require a lot of money and time to treat them. Negative pressure wound therapy (NPWT) is a device that can be used to treat challenging wounds. A piece of foam is contoured to fit a wound and is then attached to a suction device to create negative pressure, also known as a vacuum. This is thought to help with wound healing because it draws away bacteria and pus from the wound and encourages blood flow and cell movement into the wound. Since NPWT was invented in 1991, more 300 million wounds have been treated using it. Compared to conventional wound dressings, NPWT is believed to be cheaper and more effective. It has truly revolutionized wound care.
The VAC Therapy system is the first commercially available NPWT device. It has several advantages but running it can be very expensive. The goal of this study was to reduce the running costs of the VAC therapy system by modifying it. This was achieved by attaching an additional drainage canister to the main canister so that it would have to be replaced less frequently.
This study aims to recruit around 50 patients with surgical wounds who have been admitted to the hospital, to compare the total costs of their treatment when the modified VAC system is used compared to the regular VAC system. The study's finding should help reduce the costs of running the VAC system, if the modified system is found to be effective. This is even more important in countries where the healthcare system is underfunded.

Who can participate?
Adults over the age of 17 who are admitted to the Department of Plastic and Reconstructive Surgery at Ghazi Al Hariri Hospital for Surgical Specialties in Baghdad Medical City, Iraq.

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups will have a VAC therapy device applied to their wounds. One group's VAC system will have an the additional drainage canister fitted to the system, which will mean that the canister does not have to be changed as often. The other group will have a regular VAC system. The wounds will be assessed regularly by someone who does not known which group the participant is in, to determine when the wounds

are healed. The study will last 3 years. The total treatment costs for each participant will be calculated and used to compare the treatment costs between the two groups.

What are the possible benefits and risks of participating?
There will be no immediate direct benefits or risks to those taking part. They will all receive treatment using the VAC system. But there should be benefits to future patients who require the VAC device, as the cost-savings can be directed towards providing the treatment to even more patients.

Where is the study run from?
The Department of Plastic and Reconstructive Surgery at Ghazi Al Hariri Hospital for Surgical Specialties in Baghdad Medical City, Iraq.

When is the study starting and how long is it expected to run for?
January 2016 to October 2019

Who is funding the study?
There is no external funding for this study.

Who is the main contact?
Dr Waleed Albayati, dr.waleed1986@yahoo.com

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomised controlled trial assessing the impact of a modification to the negative pressure wound therapy on total treatment costs for acute and chronic wounds

Study objectives
A simple modification to the VAC therapy system can result in significant cost reduction in consumable daily costs

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/03/2016, Iraqi Health Ministry Ethical Committee, ref: 124

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Acute and chronic wounds

Interventions
Patients with acute complex wounds or chronic wounds were divided randomly into two groups using randomization generator software. Group A received treatment with conventional negative-pressure wound therapy (NPWT) device while Group B treated with a modified NPWT device with an additional where an intermediary canister is attached to the primary drainage canister, to reduce the amount of ActiVAC canisters that are changed. All the patients were followed until the closure of the wounds.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ACTIV.A.C.™

Primary outcome measure
1. Duration of therapy, defined as the time needed to get a wound ready for closure either by skin graft of flap. This time determined clinically by the supervising reconstructive surgery consultant depending on the wound bed score, which is an objective method to determine the status of wound and it is readiness for further intervention. This information is recorded in the patient's medical records and separately in the study records.
2. Number of dressings calculated by assuming that the dressing was changed every 3 days as per manufacturing company advice
3. Number of canisters used calculated by the total number of 300-ml canisters used for each patient, which are changed when the Activac device alarm system is activated. The modified NPWT device uses a 1000-ml canister, which is is reusable, so the number of canisters is fixed at one for each patient in this group. This information is recorded in the patient's medical records and separately in the study records.
4. Total treatment cost assessed assessed at the end of therapy duration for each patient separately and for each group, by collecting the cost of disposable canisters, dressing and the rent cost of the Activac device. The cost of each item is determined according to the local hospital bills and global prices.

Secondary outcome measures
1. Patient age determined by reviewing patient medical records
2. Patient sex determined by reviewing patient medical records
3. Location of the wound determined by reviewing patient medical records
4. Associated comorbidities determined by reviewing patient medical records
5. Wound bed score assessed by the supervising reconstructive surgeon at regular intervals (every 3 days during the application of dressing) and the final score determined at the end of the therapy.

Overall study start date
10/01/2016

Completion date
17/10/2019

Eligibility

Key inclusion criteria
Patients with acute complex or chronic non-healing wounds that required surgical intervention to facilitate healing or closing of the wound

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
35

Total final enrolment
52

Key exclusion criteria
1. Malignancy near the wound site
2. Osteomyelitis
3. Peripheral vascular disease

Date of first enrolment
01/07/2016

Date of final enrolment
01/05/2019

Locations

Countries of recruitment
Iraq

Study participating centre
Department of Plastic and Reconstructive Surgery Teaching Hospital
Ghazy Al Hariri Hospital
Baghdad
Iraq
45712

Sponsor information

Organisation
Department of Plastic & Reconstructive Surgery

Sponsor details
Ghazy Al Hariri Hospital for Surgical Specialities
Baghdad Medical City
Bab Al Muadam
Baghdad
Iraq
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator-funded

Results and Publications

Publication and dissemination plan
We intend to publish in a wound-related or plastic surgery-related journal by the end of 2018.

Intention to publish date
30/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Waleed Khalid Albayati (Dr.waleed1986@yahoo.com). Data includes all the patients' variables that were measured in this study. Data in electronic form will be available upon request or demand for 5 years. Consent was obtained from each patient.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	25/08/2021	17/03/2022	Yes	No