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The usefulness of vacuum-assisted closure therapy in postoperative abdominal wound dehiscence

Submission date
18/05/2020

Recruitment status
No longer recruiting

Registration date
31/05/2020

Overall study status
Completed

Last Edited
02/06/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Postoperative abdominal wound dehiscence (PAWD) is also known as a burst abdomen. It can occur on average during the 7th day after surgery (postoperative) but may range between 1-23 days. An open abdomen or laparotomy wound is a general term for when the abdomen which is left intentionally open without any primary closure in critically ill patients where definitive repair is performed after a few weeks. Although there are a good number of studies on the effect of vacuum-assisted closure (VAC) therapy for open abdomen, very few studies have reported its usefulness in postoperative abdominal wound dehiscence. Therefore the aim of this study is to find out whether VAC therapy promotes healing in postoperative abdominal wound dehiscence.

Who can participate?
All patients aged over 18 who develop abdominal wound dehiscence in the postoperative period, excluding critically ill and ICU, bile leak patients

What does the study involve?
All patients are treated with VAC therapy and wound healing is assessed.

What are the possible benefits and risks of participating?
Possible benefits include improvement from local sepsis, early ambulation (walking), and early discharge from hospital. Possible risks include bleeding and pain.

Where is the study run from?
All India Institute of Medical Sciences Bhubaneswar (India)

When is the study starting and how long is it expected to run for?
May 2017 to December 2019

Who is funding the study?
All India Institute of Medical Sciences Bhubaneswar (India)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
researchregistry5597

Study information

Scientific Title
Assessing the effect of vacuum-assisted closure therapy in postoperative abdominal wound dehiscence: an observational study

Study objectives
Vacuum-assisted closure therapy (VAC) is a well-known technique used for the treatment of diabetic wounds, infected orthopaedic wounds, sternotomy wounds. Systematic reviews reported good facial closure rates with VAC therapy in open abdomen. Whereas very few studies reported its usefulness in postoperative abdominal wound dehiscence and most of them are retrospective studies. Therefore the researchers designed a prospective study on VAC therapy to know its effectiveness in PAWD. The aim of this study is to measure the effect of VAC therapy in terms of decreasing local sepsis, promoting granulation tissue and thereby achieving early cutaneous cover in postoperative abdominal wound dehiscence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/07/2017, Institutional Ethics Committee, All India Institute of Medical Sciences, Bhubaneswar (Institute research cell, AIIMS, Bhubaneswar, Odisha, 751019, India; +91 (0) 9438884016; iec@aiimsbhubaneswar.edu.in), ref: IEC/AIIMS/BBSR/PG THESIS/2017-18/21

Study design
Single-centre observational longitudinal cross-sectional study

Primary study design
Observational

Secondary study design
Longitudinal 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
Postoperative abdominal wound dehiscence

Interventions
The data, including wound type, size for each patient are collected in a standardized manner. Then under sterile conditions, adequate debridement and saline irrigation are done followed by paraffin-impregnated gauze pieces applied in at least two layers over the wound in such a way

that the bowel is completely covered. It serves as a protective layer, and the purpose of this layer is to completely prevent contact between the bowel and the polyurethane (PU) foam. The foam is cut as per the wound size and placed over paraffin gauze in such a way that it has contact with all the edges. An adhesive drape is then applied over the foam. A 2-cm hole is made at the center of this drape to allow a suction drain to fit over it. The suction tube is then connected to a commercially available VAC device. The negative pressure was set at a range of 75-100 mmHg, either in a continuous or intermittent mode. The dressings were changed every 48-72 hours depending on the exudates collected in the canister. Therapy continued until granulation or apposition of tissue is achieved and aborted in case of excessive pain or bleeding.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. Duration for achieving a cutaneous cover or granulation tissue without any local sepsis:
1.1. Cutaneous cover: the time (days) from the day of VAC application until the wound is covered with skin grafting or secondary suturing or by secondary intion of healing
2.2. Granulation tissue appearance and no local sepsis: the day when there is no or minimal pus discharge with healthy red granulation tissue appearance after the 1st VAC application. A macroscopic objective observed after each VAC application
2. Duration of hospital stay, measured using medical records as the time (days) between the 1st VAC application until discharge from the hospital

Secondary outcome measures
1. Total leukocyte counts measured with a routine complete blood picture before 1st VAC and after the 2nd VAC
2. Wound size measured with a standard scale before and after application of VAC
3. Amount of negative pressure applied: the average amount of negative pressure (mmHg) applied for each patient measured after the last VAC
4. Total sessions of VAC dressings required: each VAC dressing is noted in the record and the total sessions of dressings applied were noted at the time of discharge
5. Total cost of therapy: the cost applied for each VAC and total amount calculated after the end of last VAC
6. Incisional hernia measured clinically as well as by ultrasound during 6 months of follow up

Overall study start date
20/05/2017

Completion date
26/12/2019

Eligibility

Key inclusion criteria
1. Patients who underwent VAC. therapy for sheath dehiscence developed in the postoperative period between 2017 to 2019
2. Patients above 18 years of age including both males and females

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
46

Total final enrolment
46

Key exclusion criteria
1. Patients who had only skin dehiscence
2. Postoperative ascites
3. Bile leak
4. Entero cutaneous fistulas
5. Metastatic carcinoma
6. Multi-organ dysfunction
7. Critically ill patients on a ventilator
8. Those who needed further exploration

Date of first enrolment
10/08/2017

Date of final enrolment
29/07/2019

Locations

Countries of recruitment
India

Study participating centre
All India Institute of Medical Sciences, Bhubaneswar, Odisha, India
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/029mnbn96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
All India Institute of Medical Sciences Bhubaneswar

Results and Publications

Publication and dissemination plan
The researchers are intending to publish the results as they feel that the results can be very much put in to use for postoperative wound care relating to burst abdomen.

Intention to publish date
31/05/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr E Vamshi Krishna (vamshi25krishna@gmail.com).

IPD sharing plan summary
Available on request