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Preventing abdominal surgical wound infections with negative pressure wound therapy dressings

Submission date
12/05/2020

Recruitment status
No longer recruiting

Registration date
22/05/2020

Overall study status
Completed

Last Edited
15/11/2021

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Surgical site infections (SSIs) are the most common cause of healthcare-associated infections in patients undergoing surgery. SSIs also contribute to increased morbidity, mortality, prolonged hospitalisation, impaired quality of life, and increased healthcare costs. It is unclear whether topical negative pressure wound therapy (NPWT) dressings can reduce the risk of SSIs in patients undergoing abdominal surgery. The aim of this study is to assess the effectiveness of NPWT at reducing superficial SSI following open abdominal surgery.

Who can participate?
Patients aged 16 years and over who are undergoing an “open” abdominal operation (a larger abdominal cut than smaller “keyhole” surgery)

What does the study involve?
Patients will be randomly allocated to receive either a “standard” dressing (a large “band-aid” covered simple dressing) or a negative pressure wound therapy dressing after surgery. This dressing will remain in place until days 5-7 post-surgery, after which it will then be removed. The total follow-up is for 30 days after surgery.

What are the possible benefits and risks of participating?
Patients with a silver allergy will not be eligible to participate in the study, as there is silver within the NPWT dressing. A benefit of participating may be determining whether NPWT does actually decrease the incidence of SSIs.

Where is the study run from
Blacktown and Westmead Public Hospitals (Australia)

When is the study starting and how long is it expected to run for?
July 2014 to October 2020

Who is funding the study?
The NPWT dressings and devices were provided by KCI Medical. There is no other funding received for this study.

Who is the main contact?
Dr Grahame Ctercteko
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Contact information

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Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HREC/14/WMEAD/321

Study information

Scientific Title
Surgical Wound Infection Prevention by Early Intervention using Topical negative pressure therapy – the SWIPE IT trial

Acronym
SWIPE IT

Study objectives
That negative pressure wound therapy (NPWT) dressings decrease the incidence of superficial surgical site infection (SSI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/07/2015, Western Sydney Local Health District Ethics Committee (Research & Education Network Building, Westmead Hospital, Cnr Hawkesbury Rd and Darcy Rd, Westmead, NSW, 2145, Australia; +612 (0)8890 8249; wslhd-researchoffice@health.nsw.gov.au), ref: HREC /14/WMEAD/321

Study design
Prospective non-blinded phase III multi-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Superficial surgical site infection

Interventions
Computer-assisted randomisation was used to assign patients to either the control (standard dressing) or interventional arm (NPWT) in a 1:1 allocation scheme. The outcome of randomisation was made available to the operating surgeon upon skin closure to avoid performance bias. Patients and study investigators were not blinded to the study intervention.

After skin closure, patients in the intervention arm had an NPWT (Prevena) dressing placed over the entire incision, with a pre-set negative pressure of 125 mmHg.

Patients in the control group had either a Cutiplast or Comfeel dressing placed covering the entire wound.

These dressings were left in place until days 5-7 post-operatively (at which time they were then removed).

Intervention Type

Device

Phase
Phase III

Primary outcome(s)
The incidence of superficial SSI diagnosed on the basis of the following CDC criteria:
1. Purulent drainage, with or without laboratory confirmation, from within the wound
2. Organisms isolated from an aseptically obtained culture of fluid from the incision
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness and superficial incision deliberately opened by the surgeon, unless incision is culture-negative
4. Diagnosis of superficial incisional SSI by the independent assessor
Assessed by the treating doctors on postoperative day 5-7 and then on day 30

Key secondary outcome(s))
1. Deep and organ space SSI as measured by Centre for Disease Control and Prevention Surgical Site Infection criteria at Days 7 and 30 post-surgery (Deep = Infection involves deep tissues, such as fascial and muscle layers; Organ space = infection involves any part of the anatomy in organs and spaces other than the incision, which was opened or manipulated during operation)
2. Length of stay post-operatively, measured in days from date of hospital admission to date of hospital discharge
3. Fascial wound dehiscence, measured by fascial breakdown at Days 7 and 30 post-surgery (either a relook surgery or on imaging)
4. Superficial wound dehiscence, defined as any separation of the skin not associated with an SSI, at Days 7 and 30 post-surgery
5. Seroma: presence of serous fluid in the surgical wound either upon physical exam or on imaging, assessed at Days 7 and 30 post-surgery
6. Haematoma: presence of blood-stained fluid in the surgical wound either upon physical exam or on imaging, assessed at Days 7 and 30 post-surgery

Completion date
31/10/2020

Eligibility

Key inclusion criteria
1. Age 16 years or over
2. Any gender
3. Undergoing elective or emergency laparotomy
4. All general surgical sub-disciplines were potentially included in the study
5. Patients undergoing minimally invasive surgery converted to laparotomy were also included

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Total final enrolment
127

Key exclusion criteria
1. Hypersensitivity to silver
2. Patients without capacity to consent, pregnancy
3. Patients with pre-existing laparostomy

Date of first enrolment
14/10/2015

Date of final enrolment
05/07/2019

Locations

Countries of recruitment
Australia

Study participating centre
Westmead Hospital
Corner Hawkesbury Road and Darcy Road
Westmead
Australia
2145

Study participating centre
Blacktown Hospital
18 Blacktown Road
Blacktown
Australia
2148

Sponsor information

Organisation
Westmead Hospital

ROR
https://ror.org/04gp5yv64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Westmead and Blacktown Hospitals

Funder Name
KCI (providing the NWPT dressings/devices)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Angelina Di Re (Angelina.dire@gmail.com). Data is currently available as a de-identified coded excel spreadsheet. It will be available for 5 years post study publication in a peer-reviewed journal. Data may be shared to scientific researchers, but this will need to first be approved by the Western Sydney Local Health District Ethics Committee, as specific patient consent for this has not been specifically obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/11/2021	15/11/2021	Yes	No
Participant information sheet	Participant information sheet version V02	11/11/2025	11/11/2025	No	Yes
Protocol file		20/10/2014	08/06/2020	No	No