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The role of PREVENA vacuum dressings in patients undergoing breast surgery affecting both sides

Submission date
04/06/2020

Recruitment status
No longer recruiting

Registration date
13/08/2020

Overall study status
Completed

Last Edited
07/06/2023

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
Bilateral mammoplasty surgery is a very commonly performed procedure but unfortunately can lead to significant wound complications such as infection, skin/nipple/breast tissue loss, seroma (fluid collection inside the breast) and wound dehiscence (wound opening). Recently a negative pressure dressing called PrevenaTM has become available and has been demonstrated to reduce wound complication rates by up to 4-fold in other types of surgery (abdominal, vascular, orthopaedic joint replacement procedures). There is currently no evidence for PrevenaTM dressing use in breast surgery. This study is designed to establish whether PrevenaTM dressings can help reduce the potential complications we see in mammoplasty surgery. The PrevenaTM Incision Management System is a dressing that is applied to a surgical wound after an operation. It applies a negative pressure (like a vacuum) to the wound which may reduce the risk of developing wound complications. The dressing has a tube which attaches to the suction machine and battery (approximately the size of a mobile phone). This can be carried in your bag or pocket. The PrevenaTM dressing is designed to remain in place for one week.

Who can participate?
Patients who are about to undergo a bilateral mammoplasty operation

What does the study involve?
At the end of their operation participants will have a conventional dressing applied to one breast and a PrevenaTM dressing applied to the other. Both dressings will remain in place for 1 week. When they attend for their next three normal follow up appointments, the researchers will assess their wound healing and any complications and record these findings for the study. At visit 1 (1 week after surgery) participants will attend the Plastics Dressing Clinic at the RVI (New Victoria Wing) for a wound review appointment. This is a standard wound check appointment that participants would be asked to attend regardless of whether they were taking part in the study. Dressings on both breasts will be removed at this stage in order to assess healing. Following the wound check with the plastic surgery nurse, the research nurse will then also assess the wounds to document any healing problems or complications for the study. After this assessment, simple (conventional) dressings will be placed on the wounds as required

(sometimes no further wound dressings are needed at this stage). Note that the PrevenaTM dressing is only used for the first week. If further dressings are necessary after this first week, conventional dressings will be used for either/both breasts.
At visit 2 (2 weeks after surgery) participants will have an appointment in the breast clinic with the surgical team where they will review the results and discuss whether any further treatment is required. This is a standard appointment that participants would be asked to attend regardless of their involvement in the study. The research nurse will also be present in the clinic and following consultation with the surgical team, the nurse will perform the same wound assessments that were carried out at one week after surgery.
At visit 3 (6 weeks after surgery) participants will attend an appointment to attend the oncoplastic clinic for a review of the cosmetic appearance following surgery and to ensure that there have been no wound healing issues. Again, this is an appointment that they would be asked to attend regardless of their involvement in the study. Following the consultation with the surgeon, the research nurse will carry out the same wound check as previously in order to document study data. If there appears to be signs of infection or swelling on any of the three follow up appointments, occasionally it is necessary to arrange an ultrasound scan during the visit to the hospital. This is to establish whether there is an underlying fluid collection within the breast (sometimes if there is a significant collection, it is necessary to drain it with a needle to help clear up the infection or swelling). If this is performed, the results of the ultrasound will also be documented for study purposes.

What are the possible benefits and risks of participating?
The PrevenaTM dressing system is very safe and is already used frequently in other types of surgery. It is contraindicated in patients with an allergy to silver; consequently, participants who are allergic to silver are unfortunately unable to take part in this trial. There are no other contraindications.
The PrevenaTM dressing is slightly more inconvenient than a normal dressing as it has a tube attached to the dressing, which leads to a battery pack (approximately the size of a mobile phone). Consequently, this pack will need to be carried for the first week following surgery (in a bag or clothes pocket). Most patients don’t find this to be much of an inconvenience. There are no significant disadvantages to taking part in this study, aside from the three appointments (above) taking a little longer than for someone not involved in the trial.

Where is the study run from?
Royal Victoria Infirmary (UK)

When is the study starting and how long is it expected to run for?
January 2019 to August 2023

Who is funding the study?
The study is funded by ACELITY IIS and this company is also providing the PREVENA dressings

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
254703

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 254703

Study information

Scientific Title
The role of PREVENA vacuum dressings in patients undergoing bilateral mammoplasty surgery

Acronym
PREVENA

Study objectives

In the PREVENA dressing arm, the wound complication rate will be lower than that of the conventional dressings (control) arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/04/2019, North East - Tyne and Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0) 207 1048084; tyneandwearsouth.rec@hra.nhs.uk), ref: 19/NE/0069

Study design
Single-centre blinded study randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients undergoing a mammoplasty procedure for cancer

Interventions
This is a single centre blinded study (wound assessing clinicians are blinded). Patients are randomised in a 1:1 fashion. All enrolled patients will be undergoing bilateral surgery and shall be included in both the control and intervention arms of the study. Patients will have a conventional dressing (control arm) applied to one breast and a PREVENA Incision Management System (intervention arm) applied to the contralateral breast. At this institution, conventional dressings comprise steristrips and an Opsite dressing. Occasionally (in the case of allergy /sensitivity), Cosmopore dressings or Dermabond glue are used.

The laterality of the control and intervention arm dressings will be randomised after skin closure, just prior to dressing application. Randomisation will be conducted by opening a sealed blank envelope at the end of the operation, which will state the laterality of the Prevena dressing for the patient, with an equal chance of being the “cancer side” or the “non-cancer side”. As randomisation will be performed after skin closure, surgeons will essentially be blinded. Clearly, it is not possible to blind the patient. At 1-week follow up, the patient will be seen by the surgeon who will remove the dressings. After this clinical follow-up appointment, the research nurse will review the patient to record the study outcome measures as listed above. Research personnel collecting data will be blinded with regards to the laterality of the dressings. In cases requiring aspirating of collections, the ultrasonographer will be blinded as dressings will have already been removed by the surgeon.

Intervention Type
Other

Primary outcome(s)
The overall occurrence of surgical site complication (SSC) rate at 6 weeks. Patients who experience any of the following complications (infection, necrosis, wound dehiscence) will be counted as an occurrence.

Key secondary outcome(s))
Assessed clinically 1, 2 and 6 weeks unless otherwise stated:
1. Infection occurrence as binary outcome (yes/no) for each patient
2. Clinical assessment using the ASEPSIS scoring system
3. USS for all patients who have clinical signs of infection (as per validated score system)
4. If collection seen, USS guided aspiration, documenting volume and fluid type (1. Pus, 2. Seroma, 3. Fat necrosis)
5. Skin/nipple necrosis evaluated in the following ways:
5.1. Skin/nipple occurrence as binary outcome (yes/no) for each patient
5.2. Percentage of skin necrosis of the total wound length for each patient
5.3. Percentage of nipple necrosis of the total nipple area for each patient
6. Wound dehiscence occurrence as binary outcome (yes/no) for each patient
7. Pain measured using visual analogue scale (1-10)
8. Return to theatre (including laterality of problem leading to re-admission presentation) at 30 days
9. Re-admission rates (including laterality of problem leading to re-admission presentation) at 30 days

Completion date
02/08/2023

Eligibility

Key inclusion criteria
1. Patients undergoing bilateral Wise pattern or vertical scar mammoplasty surgery
2. Indication for surgery: unilateral oncoplastic procedure with simultaneous contralateral symmetrising surgery
3. English speaking
4. Capacity to consent
5. Age 18-80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
Female

Key exclusion criteria

1. Sensitivity to silver (PREVENA is contraindicated)

Date of first enrolment
13/02/2020

Date of final enrolment
28/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
KCI Europe Holding BV

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes