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Prospective post-market study of an incision management system in closed surgical incisions

Submission date
08/12/2020

Recruitment status
No longer recruiting

Registration date
01/09/2021

Overall study status
Completed

Last Edited
15/12/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
The aim of this study is to compare the safety and performance of closed incision Negative Pressure Therapy (ciNPT) using PREVENA™ Dressings that do not contain silver with negative pressure therapy using the V.A.C.® GRANUFOAM™ Dressing over closed surgical incisions and to show that there is none to little difference between the two dressing types.

Who can participate?
Patients aged 22 and over undergoing surgery with a suitable surgical incision

What does the study involve?
The standard V.A.C.® Therapy group will be enrolled first. After enrollment is complete for the control group, the treatment group will be enrolled beginning with the PREVENA PLUS™ CUSTOMIZABLE™ Dressing-No Ag and then the PREVENA™ PEEL & PLACE™ Dressing-No Ag. Participants will have a dressing placed over the sutured or stapled incision immediately after surgery. The dressing will be worn for 5-7 days after surgery before stopping the negative pressure and dressing removal. Participants will return for a 30-day follow up visit.

What are the possible benefits and risks of participating?
The PREVENA™ Dressings (No Ag) are intended to manage the environment of closed surgical incisions and surrounding intact skin in patients at risk for developing postoperative complications, such as infection, by maintaining a closed environment by applying negative pressure therapy to the incision.
The V.A.C.® GRANUFOAM™ Dressings, when used on closed surgical incisions, are intended to manage the environment of the surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates by applying negative pressure wound therapy.
Possible risks from participating in the study are:
Skin and tissue risks: skin surface stripping, bruising, softening and breakdown of skin tissue from prolonged exposure to moisture, minor soft tissue damage, local skin reaction (ie, redness, rash, significant itching, hives), minor bleeding, pain.
Other risks: bleeding complications (associated with the surgical procedure, other therapies, and medical conditions), increased risk of bleeding from the incision associated with the use of blood

thinners, localized infection, exposure-related infection, first-degree burn (if therapy unit gets warm), minor drying of the wound (due to dressing leak), moderate soft tissue damage (i.e., due to trip hazard, tubing entanglement), worsening of the wound (due to lack of visibility of incision site through dressing), physical discomfort, disruption of the surgical incision.

Where is the study run from?
Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2020 to February 2022

Who is funding the study?
KCI Medical (Ireland)

Who is the main contact?
Mr Jens Vydt
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
292120

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
KCI.PREVENA.2020.01, CPMS SURG 47748, IRAS 292120

Study information

Scientific Title
Prospective, active comparator-controlled, post-market study observing the safety and performance of the PREVENA™ (No Ag) incision management system compared to negative pressure wound therapy (NPWT) in closed surgical incisions in 40 study participants

Study objectives
This study is not statistically powered, therefore, no hypothesis testing will be conducted on primary or secondary endpoints. However, the objective of this study is to compare the safety and performance of ciNPT using PREVENA™ Dressings that do not contain silver with negative pressure therapy using the V.A.C.® GRANUFOAM™ Dressing over closed surgical incisions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2021, London - West London & GTAC Research Ethics Committee (Health Research Authority, NHSBT Newcastle Blood Donor Centre, Holland Dr, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8171; kevin.ahmed@hra.nhs.uk), REC ref: 21/PR/0578

Study design
Multicenter post-market prospective open-label non-randomized cohort active comparator-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Incision management therapy for patients undergoing a surgery with an applicable surgical incision

Interventions
Control: Negative Pressure Wound Therapy (NPWT) Dressing:
V.A.C.® GRANUFOAM™ with nonadherent interface layer
To be used along with one of the following negative pressure therapy units as a source of continuous 125 mmHg of negative pressure therapy:
ACTIV.A.C.™ Therapy Unit
V.A.C.ULTA™ Therapy Unit
V.A.C.VIA™ Therapy Unit

Treatment: Closed Incision Negative Pressure Therapy (ciNPT) Dressing
PREVENA™ PEEL & PLACE™ Dressing (20 cm) (No Ag) or PREVENA PLUS™ CUSTOMIZABLE™ Dressing (No Ag)
To be used along with the following source of continuous 125 mmHg of negative pressure therapy: PREVENA PLUS™ 125 Therapy Unit.

The standard VACUUM ASSISTED CLOSURE™ Therapy (V.A.C.® Therapy) group will be enrolled first. After all enrollment (20 participants) is complete for the control cohort, the treatment group (20 Subjects) will be enrolled beginning with the PREVENA PLUS™ CUSTOMIZABLE™

Dressing-No Ag (10 subjects) and then the PREVENA™ PEEL & PLACE™ Dressing-No Ag (10 participants).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
PREVENA™ PEEL & PLACE™ Dressing, PREVENA PLUS™ CUSTOMIZABLE™ Dressing, PREVENA PLUS™ 125 Therapy Unit, VACUUM ASSISTED CLOSURE™ Therapy (V.A.C.® Therapy), V.A.C.® GRANUFOAM™, ACTIV.A.C.™ Therapy Unit, V.A.C.ULTA™ Therapy Unit, V.A.C.VIA™ Therapy Unit

Primary outcome(s)
The incidence of treatment-related adverse events from treatment application, measured using number of events and subject incidence of Treatment Related Adverse Events (TRAE) reported until 30-day follow-up

Key secondary outcome(s))
The incidence of surgical site complications (SSC) and surgical site infections from treatment application, measured using occurrence of any SSC reported from treatment start date until 30-day follow-up

Completion date
01/02/2022

Eligibility

Key inclusion criteria
Pre-operative inclusion criteria:
The particpant:
1. Is able to provide their own informed consent
2. Is ≥22 years of age

Intra-operative inclusion criteria:
The particpant:
3. Has a surgically closed incision with a length of less than 20 cm such that the entirety of the incision can be covered by the negative pressure dressing
4. Has a wound that meets CDC Wound Classification 1 or 2 (Clean or Clean-Contaminated)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
42

Key exclusion criteria
Pre-operative exclusion criteria:
The particpant:
1. Has one or more of the following conditions:
1.1. Uncontrolled diabetes
1.2. BMI greater than 35
1.3. Is currently smoking
2. Has a dehisced surgical wound in the area of the planned incision site
3. Has an oncologic wound in the area of the planned incision site
4. Has an open wound in the area of the planned incision site
5. Has an allergy to acrylic adhesives
6. Is pregnant at the time of study treatment and the planned surgical procedure is an operation other than a Cesarean section (C-section)
7. Is breastfeeding and the planned incision is located on the breast or the area near the breast
8. Is participating in another interventional clinical trial
9. Has signs/symptoms or a documented systemic infection (bacterial, viral or fungal)

Intra-operative exclusion criteria:
10. Has a wound that meets CDC Wound Classification 3 or 4
11. Has cellulitis of the incision area
12. Requires use of a nonadherent interface layer containing silver
13. Has inadequate hemostasis of the incision
14. Has ischemia to the incision or incision area
15. Is using V.A.C. VERAFLO™ Therapy (instillation) over the incision site
16. Requires the use of drainage or pain control devices that exit through the surgical incision, or the area covered by the dressing/drape

Date of first enrolment
02/07/2021

Date of final enrolment
22/11/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nuffield Orthopaedic Centre
Oxford University Hospitals NHS Foundation Trust

Oxford
United Kingdom
OX3 7HE

Study participating centre
St Mary's Hospital
Manchester University NHS Foundation Trust
Manchester
United Kingdom
M13 9WL

Study participating centre
St Thomas' Hospital
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
KCI Medical (Ireland)

ROR
https://ror.org/0137xm018

Funder(s)

Funder type
Industry

Funder Name
KCI Medical (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are not expected to be made available due to the high commercial sensitivity of the study products

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		14/12/2022	15/12/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes