

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

Submission date 08/12/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/09/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/12/2022	Condition category Surgery	<input type="checkbox"/> 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

thinner, 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

292120

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

03/06/2020

Completion date

01/02/2022

Eligibility

Key inclusion criteria

Pre-operative inclusion criteria:

The participant:

1. Is able to provide their own informed consent
2. Is ≥ 22 years of age

Intra-operative inclusion criteria:

The participant:

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

Age group

Adult

Sex

Both

Target number of participants

40

Total final enrolment

42

Key exclusion criteria

Pre-operative exclusion criteria:

The participant:

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 dehiscent 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. VERAFLOR™ 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

England

United Kingdom

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

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Study participating centre

St Thomas' Hospital

Guy's and St Thomas' NHS Foundation Trust

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KCI Medical (Ireland)

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Sponsor type
Industry

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ROR
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Funder(s)

Funder type
Industry

Funder Name
KCI Medical (Ireland)

Results and Publications

Publication and dissemination plan

At this time, there is no plan to publish the data from this study. This data is intended to be post-market data to support the clinical evidence of the product. The final report is planned for 25/03/2022.

Intention to publish date

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