

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

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

Mr Jens Vydt

**Contact details**

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## Additional identifiers

**Integrated Research Application System (IRAS)**

292120

**Protocol serial number**

KCI.PREVENA.2020.01, CPMS SURG 47748

## 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 participant:

1. Is able to provide their own informed consent
2. Is  $\geq 22$  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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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 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. 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

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?
<a href="#">Basic results</a>		14/12/2022	15/12/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No