

PICS PREVENA

PREVENTION OF INFECTIONS IN CARDIAC SURGERY (PICS) PREVENA STUDY

A CLUSTER-RANDOMIZED FACTORIAL CROSSOVER TRIAL,
COMPARING ANTIBIOTIC MONO-PROPHYLAXIS WITH
CEFAZOLIN VS. DUAL-PROPHYLAXIS WITH CEFAZOLIN PLUS
VANCOMYCIN AND CONVENTIONAL WOUND DRESSING VS.
PREVENA NEGATIVE-PRESSURE WOUND MANAGEMENT

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Hypotheses

- 1) that adding vancomycin to cefazolin for pre-operative prophylaxis reduces complex sternal surgical site infections
- 2) that the use of negative pressure wound dressing (PREVENA) reduces complex sternal surgical site infections in obese and/or diabetic patients

Design

- Cluster cross-over factorial RCT design
- Order of arms randomized, e.g. A → B → C → D
- Study arm standard of care for majority of patients (consent waived)
- Duration of study arm variable, aiming for 500/arm/site – 2 sites (total of 4,000 participants)

	Standard dressing	Prevena
Mono-prophylaxis	Cefazolin 2-3g pre-op, intra-op, and 2x post-op Standard dressing	Cefazolin 2-3g pre-op, intra-op, and 2x post-op Prevena*
Combination prophylaxis	Cefazolin as above Vancomycin 1-1.5g pre-op, 1x post-op q12h Standard dressing	Cefazolin as above Vancomycin 1-1.5g pre-op, 1x post-op q12h Prevena*

* Patients with BMI>30 and/or diabetes mellitus

Interventions

Antibiotic mono-prophylaxis:

- Cefazolin 2g (or 3g if greater than 120kg body weight) will be given within an hour of surgery, followed by one intra-operative dose of cefazolin at 4 hours after the first dose or upon wound closure (whichever comes first), and finally two post-operative doses q8h.

Antibiotic dual prophylaxis:

- As above plus vancomycin at roughly 15mg/kg body weight intravenously, i.e. 1g, or 1.5g if greater than 85kg body weight.
- No intra-operative dose of vancomycin will be given, and a single second dose will be given 12 hours after the first dose.

Interventions *(cont'd)*

Standard wound dressing:

- Non-negative wound dressing as standard of care at the study site.

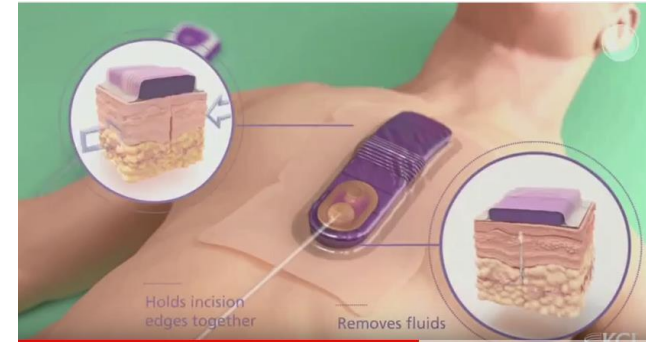
Prevena – negative pressure wound management system:

- Prevena will be applied to all diabetic and/or obese patients (BMI >30kg/m²) at the end of surgery on the sternal as well as vein harvest site (if open saphenous vein harvest) in the OR and left in place for 7 days.
- If patient is discharged prior to 7 days, they can go home with the Prevena.

Prevena

WHAT IS PREVENA™ THERAPY?

PREVENA™ Therapy is a portable, disposable system, which uses **negative pressure** (like a vacuum) to protect your incision.



Prevena 20cm for Sternum



Prevena Plus 90cm for leg



- Prevena applied post-surgery on closed wound in OR on patients with BMI >30 and/or diabetes mellitus
- Remains on patient until post-operative day 7

Eligibility

Centres with >300 open-heart cardiac procedures annually

Inclusion Criteria

- > 18 years of age undergoing open-heart surgery (sternotomy, including minimally-invasive sternotomies)

Exclusion Criteria

- On systemic antibiotics or with an active bacterial infection at the time of surgery
- Previously enrolled in this trial
- MRSA colonized patients
- Allergic to vancomycin, beta-lactam or silver, precluding the use of vancomycin, cefazolin or Prevena respectively
- Participation in other studies interfering with this trial

Outcomes

Pilot/Vanguard Feasibility:

- Adherence to wound management system
- Adherence to antibiotic regimen
- Loss of follow-up

Eventual full trial - Primary clinical outcome:

- Deep and/or organ-space sternal SSI (CDC/NHSN, 90 day follow-up)

Eventual full trial - Secondary clinical outcomes:

- All sternal SSIs including superficial infections
- Leg SSIs (harvest site)
- Wound dehiscence
- Laboratory confirmed *C. difficile* infection
- Mortality in patients with an active infection
- Length of ICU and hospital stay
- Pain

Follow-up – 90 Days

90 Day Visit

- Outcomes since discharge up to 90 days only



Outcomes

- Sternal Surgical Site Infections (including superficial incisional infections)
- Wound dehiscence
- Leg Surgical Site Infection
- Laboratory confirmed *C. difficile* infection
- Death
- Acute kidney injury within 7 days of surgical procedure