The use of Prevena Incision Management System on clean closed sternal midline incisions in subjects at high risk for surgical site occurrences.

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The objective of the study is to assess the performance of topical negative pressure therapy application with Prevena* Incision Management System (IMS) versus standard conventional wound therapy (SCWT) on closed median sternal incisions in patients...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON45162

Source
ToetsingOnline

Brief title
KCI.2013.Prevena.01

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
heart surgery, sternotomy

Research involving
Human

Sponsors and support

Primary sponsor: KCI-Medical

Source(s) of monetary or material Support: KCI Europe holding financiert deze studie

Intervention

Keyword: Medical Device, Prevena, Sternal midline inciscion, Wound infection

Outcome measures

Primary outcome

Incidence of surgical site infection (SSI) within 30 days postoperatively,

defined as superficial, deep, and organ space infections as per CDC guidelines.

Secondary outcome

* Sternal wound dehiscence without the presence of infection, defined as any

partial or complete separation of the skin, subcutaneous layer and or sternal

edges, with or without psuedoarthosis, and/or serosanguinous discharge from the

wound.

* Overall mortality within 3 months

Study description

Background summary

See protocol page 14

Study objective

The objective of the study is to assess the performance of topical negative pressure therapy application with Prevena* Incision Management System (IMS) versus standard conventional wound therapy (SCWT) on closed median sternal incisions in patients undergoing cardiac surgery.

Study design

A multicenter, randomized, post-marketed, non-interventional open-label clinical trial with a CE marked medical device, used in accordance with the

intended use.

Intervention

Treatment with Prevena IMS compared to conventional wound treatment.

Study burden and risks

NA

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

*Is male or female and 18 years of age or older
*Is scheduled for elective cardiac surgery for which a median sternotomy is needed (including coronary artery bypass grafting (CABG), valvular repair or replacement with or without CABG). Elective surgery is defined as planned surgery a minimum of 24 hours before the procedure.
*A total score of at least 8 points for the following risk factors:
>MAJOR risk factors receiving 8 points
*BMI * 40 kg/m2 *
>MAJOR risk factors receiving 4 points each:
*BMI of <18 kg/m2 or BMI * 30 kg/m2 *
Insulin dependent Diabetes Mellitus
*Dialysis**
>INTERMEDIATE risk factors receiving 2 points each:
*Planned bilateral mammary artery
Diabetes Mellitus (only Type I or Type II receiving oral hypoglycemic medication)
*Chronic lung disease GOLD *2
*Active smoker
*On long-term immunosuppressive medication (including but not restricted to cyclophosphamide, methotrexate, azathioprine, cyclosporine, tacrolimus or mycophenalate mofetil; or on a stable maintenance dose of prednisolone for 4 weeks or more; or will receive chronic immunosuppressant therapy during the study period (equivalent to a daily dose of * 10 mg Prednisone)
*Chronic kidney disease (defined according to the National Kidney Foundation Kidney Disease Improving Global Outcomes (KDIGO) guidelines as a GFR <30ml/min/1.73m2 for * 3 months) but not requiring preoperative renal replacement therapy (GFR can be determined using Cockroft-Gault equation tool, which is based on gender, age, weight and serum creatinine level)**
*Previous chest wall radiotherapy
*Breast size D cup or more (adding lateral tension to the wound edges according physicians discretion)
>MINOR risk factors receiving 1 point each:
*Cardiac reoperation after history of median sternotomy
*Peripheral vascular disease
*Left ventrical ejection fraction <30%
*Female gender
*Age >75 years old
*Acute myocardial infarction within 90 days before surgery
Hospitalized at least 7 days before surgery; mutually exclusive, highest score should be used
** mutually exclusive, highest score should be used;* Is capable of providing informed consent, which must be obtained prior to any study-related procedures
* Are willing and able to adhere to the study visit schedule and other protocol requirements.

Exclusion criteria

* Is pregnant
* The use of Prevena post surgery is contra indicated per investigator*s discretion
* Has a systemic infection at the time of surgery: systemic infection is diagnosed on the basis of clinical signs of sepsis with or without a positive culture of an organism from the bloodstream
* Has a remote body site infection at the time of surgery (including dental, urinary or skin soft tissue infections)
* Has current nasal swabs positive for methicillin-resistant staphylococcus aureus (MRSA)
* Has a known allergy or hypersensitivity to silver, or drape materials that contain acrylic adhesives
* Has a requirement for competing wound therapy and procedures:
* Any concomitant therapies (including other NPWT treatment) or procedures deviating from the clinical standard incision treatment or with investigational device at the location of the sternotomy (e.g. use of NPWT at other location of the body is allowed)
* Any other therapies or procedures that, in the opinion of the treating physician, would affect or influence postoperative wound stability or healing
* Is simultaneously participating in another interventional trial
* Requires use of liquid skin adhesives or glues during skin closure
* Is known to be serology positive for hepatitis B, hepatitis C, and HIV

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-11-2013
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	Prevena Incision Management System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-10-2013
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	03-12-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	27-01-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-03-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-07-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	10-06-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL44422.075.13
Other	nog niet bekend