Negative Pressure Wound Therapy for Prevention of Wound Infection after Heart Surgery

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MAYO CLINIC

IRB Protocol Template

Title: Negative pressure wound therapy for prevention of wound infection after heart surgery

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Abstract:
Wound-related complications after median sternotomy are important problems associated with increased morbidity and mortality, and lead to increase costs secondary to increase length of hospital stay and the need for repeated surgical procedures in these patients. Risk factors include: chronic obstructive pulmonary disease (COPD), smoking, diabetes, bilateral harvest of the internal thoracic artery, and, in particular, obesity have been identified as major risk factors. Breakdown of skin sutures facilitates entry of bacteria into the deeper layers and presents the initial step in the development of the majority of wound infections after median sternotomy. This theory may explain why the risk of wound infection is particularly high in obese patients, because the shear and traction forces on skin sutures are high. Negative pressure wound therapy have been used in different specialities to treat infected or open wounds, and has been proven to be of great benefit in multiple studies. Its use as a primary prevention has not been the routine after cardiac surgery in high risk patients. We hypothesize that negative pressure wound dressing application on clean skin immediately after suturing in the operating room for 6-7 days will prevent skin breakdown in the early periods after surgery and will decrease the incidence of wound related complications and infection. This may lead to a change in practice when dealing with high risk individuals. The purpose of this study was to compare a new commercially available negative pressure wound therapy (NPWT) system (Prevena Incision Management System; KCI, San Antonio, Tex) and conventional sterile dry wound dressing in a high-risk group (ie, obese patients), with special regard to wound complications and infections.
Of note the “Prevena incision management system” is an FDA-approved device with 510K clearance.

Schematic Design of the Study: There will be two groups: the first will include “Prospective non-randomized” part which will include patients who agreed to participate and have wound VAC applied to their incision postoperatively for 6-7 days (this information was collected under IRB 13-001832). The second group will include “retrospective chart review” for standard wound care after heart surgery with no wound VAC.

Aims:
Comparing the outcome of negative pressure wound therapy and conventional sterile dressing for high risk patients undergoing open heart surgery through median sternotomy

Methods

Description of Recruitment Methods:

How will subjects be identified?
Chart review and cardiac surgery database
How will subjects be contacted?
Follow-up routine postoperative visits and chart reviews
Recruitment Materials (if applicable):
Chart review

Subject Population:

Number: 950
The prospective potion will include 300 patients in whom the Prevena wound VAC system will be applied and the retrospective portion will include the remaining 650 patients.

Gender:
Male 450

Female 500
Ages: 18 to 100 years

Inclusion Criteria:

- BMI>30
- Severe COPD
- Steroid-dependent
- Type-I diabetes (insulin-dependent)
- Heart and lung transplant patients
- Preoperative tracheostomy
- Undergoing median sternotomy for open heart surgery between 2013-2014

Exclusion Criteria:

- Thoracotomy
- Type-II diabetes
- BMI<30

Step-by-Step Schedule (include all procedures, therapies – attach a table or flow chart if there are multiple procedures or visits and indicate the window of number of days in which the participant may return for follow-up visits):
N/A

Biospecimen (types, number, volume, processing, storage):
N/A

Plan for Dose Modification if Toxicity occurs (if applicable):
N/A

Statistical Considerations

Endpoints

Primary: wound infection
Secondary: wound breakdown
Length of stay
Re-operation
Mortality due to mediastinitis

Protocol form, page 2

Human Safety Aspects

Risks: Minimal risk study

Individual Subject Stopping Rules (if applicable):

DSMB (if applicable):

Members:

Charter:

Stopping Rules for Efficacy and Safety (if applicable):

Questionnaires that ask about Depression (if applicable)

Included in study? Yes ☐ No ■ If "Yes", state the plan of management for subjects with possible depression: