Vacuum-Assisted Closure versus Closed Drainage using Redon Catheters for the Treatment of Mediastinitis: a Prospective Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thoracic disorders (excl lung and pleura)
Study type	Interventional

Summary

ID

NL-OMON30622

Source
ToetsingOnline

Brief title
VAC study

Condition

- Thoracic disorders (excl lung and pleura)
- Bone and joint therapeutic procedures

Synonym
mediastinitis, sternum infection

Research involving
Human

Sponsors and support

Primary sponsor: cardioth chir
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Closed Drainage, mediastinitis, Vacuum-Assisted Closure

Outcome measures

Primary outcome

.Primary: to compare discharge after vacuum-assisted drainage or redon

drainage.

Secondary outcome

· 2 en 5-year survival (Kaplan Meier analysis)

· Quality of life (QLQ-C30 en C13)

· Duration of wound healing (termination VAC therapy, removal of redon drains)

· Freedom from mediastinal microbiological cultures

· Freedom from re-intervention

· CRP

· Failure of treatment.

Study description

Background summary

.Mediastinitis after cardiac surgery is a relatively frequent and serious complication associated with high morbidity, mortality and cost. The incidence reported in large studies is approximately 1%.
The conventional treatment of this type of mediastinitis consisted of surgical debridement and open wound healing or reconstruction with vascularized pectoral or omental tissue flaps. In 1997, vacuum-assisted closure was described as a new technique for mediastinitis treatment in order to avoid secondary surgical

closure. Several studies evaluated vacuum-assisted drainage and compared the results with conventional treatment retrospectively showing significant improvement of the outcome after vacuum-assisted drainage. Sjogren concluded from an analysis of 101 patients that vacuum-assisted closure resulted in significantly lower 90-day mortality and better overall survival compared to the conventional approach. In two more series of 42 and 68 patients, similar perioperative mortality, shortened wound healing and hospital stay, higher freedom from mediastinal microbiological cultures and more rapidly declining CRP levels were reported.
In contrast, closed drainage systems like redon drainage or continuous irrigation were proposed as alternatives for conventional treatment and vacuum-assisted closure. Closed drainage systems aim to combine either adequate wound drainage and faster wound healing resulting in more comfort for the patient compared to vacuum-assisted therapy. Two retrospective studies reported redon drainage to be superior compared to continuous irrigation. Redon drainage resulted in less treatment failure, shorter hospital stay, lower incidence of superinfections and lower mortality rate.
Currently, vacuum-assisted drainage and closed drainage using redon catheters are widely accepted methods for the treatment of mediastinitis. However, it is unknown which technique is considered to be the most effective. We hypothesize that closed drainage using redon catheters results in faster wound healing and earlier discharge. Therefore, we prospose a prospective randomized trial to compare both techniques.

Study objective

.Currently, vacuum-assisted drainage and closed drainage using redon catheters are widely accepted methods for the treatment of mediastinitis. However, it is unknown which technique is considered to be the most effective. We hypothesize that closed drainage using redon catheters results in faster wound healing and earlier discharge. Therefore, we prospose a prospective randomized trial to compare both techniques.

Study design

.Design: prospective, randomized, open
Duration: for each patient 5 years
Expected inclusion period: 2.5 years (total study duration: 7.5 years): the inclusion period is expected to start from 01-07-2007 tot 01-01-2010; the study will finish 5 years later (01-01-2015)

Flow chart:
1. diagnosis mediastinitis according CDC* criteria: tenminste 1 van de 3 criteria is voldoende voor de diagnose mediastinitis:

(1) organism isolated from culture of mediastinal tissue or fluid obtained by

needle aspiration or during surgery OR
(2) evidence of mediastinitis seen during surgery OR evidence of mediastinitis seen on histopathologic examination OR
(3) one or more of the following symptoms: fever (> 38° C), chest pain, or chest instability
AND
one or more of the following: purulent drainage from the mediastinal area, organism isolated from blood culture, organism isolated from drainage from mediastinal area, mediastinal widening on x-ray examination

2. informed consent

3. QOL: Questionary at day 0 (before the operation), 7 and 21

4. operation: debridement and cultures

VAC group: open laten gedurende 24 uur, dan VAC plaatsen (witte spons: rechtstreeks op het hart; zwarte spons: op andere weefsels), 125 mmHg zuigkracht
Redon groep: onmiddellijk sluiten sternum en huid, redons (dikste: 15 mm): 1 presternaal, minimaal 4 redons in alle open ruimtes/pockets

5. CRP and leucocytes: 3 x/week

6. Cultures of Redonpot (Redongroep) of wond (VAC groep): 2 x/week**

7. antibiotics: peroperatief starten na overleg microbioloog, continueren en beeindigen na overleg microbioloog

8. postop wondzorg en behandeling alsmede beeindiging van de behandeling onder supervisie van A. Yilmaz (533)

9. Two and five years: Phone call (survival measurement)
* Centers of Disease Control
** Aankoppelen van de Redonpotten en de wondzorg moet strikt STERIEL gebeuren

Intervention

Vacuum-Assisted Closure versus Closed Drainage using Redon Catheters .

Study burden and risks

The investigation technique (closed drainage using redon catheters) will probably result in quicker healing and discharge.

Contacts

Public
Selecteer

koekoekslaan 1
nieuwegein
NL
Scientific
Selecteer

koekoekslaan 1
nieuwegein
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients that developed mediastinitis after cardiac surgery that need re-sternotomy and fulfill the criteria of mediastinitis according to the guidelines of the US Centers for Disease Control and Prevention (CDC): (1) an organism was isolated from culture of mediastinal tissue or fluid (2) evidence of mediastinitis was seen during the operation (3) one of the following conditions, chest pain, sternal instability, or fever (> 38) was present and there was either purulent discharge from the mediastinum or an organism isolated from blood culture or culture of drainage of the mediastinal area.

Exclusion criteria

Patients who are mentally not able to chose whether to be involved in the study or not.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-08-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	ivm eventuele publicatie
CCMO	NL15612.100.07