Clinical Outcome of Postoperative Mediastinitis: Sternal Closure Versus Conventional Treatment

Published: 26-02-2008
Last updated: 08-05-2024

The aim of this study is to compare the clinical outcome and survival in patients undergoing sternal closure treatment or conventional treatment for postoperative mediastinitis. The secondary objective is to determine incidence of mediastinitis and…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30893

Source
ToetsingOnline

Brief title
Mediastinitis and sternal closure

Condition

- Other condition
- Thoracic disorders (excl lung and pleura)
- Breast therapeutic procedures

Synonym
mediastinitis, sternal infection

Health condition

mediastinitis

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Postoperative mediastinitis, Sternal closure, VAC-therapy

Outcome measures

Primary outcome

Clinical outcome and survival of the two groups: conventional versus closed sternum treatment. Outcome and survival will be determined by mortality rate, sternal closure, pain or loss of function, ability to perform same preoperative activities (work/hobby), clinical data.

Secondary outcome

Clinical outcome and survival of the subgroups of conventional treatment: omentum flap reconstruction, pectoral flap reconstruction, irrigation system and open wound treatment.

Other secondary parameters will be occurrence of mediastinitis to determine incidence and possible risk factors for mediastinitis, such as diabetes, BMI>30, COPD and number of sternal wires.

Study description

Background summary

Mediastinitis after sternotomy is a rare, but devastating complication of cardiac surgery. Postoperative mediastinitis occurs in 0,75 to 5% of patients receiving cardiac surgery. The mortality, however, is high. Different studies

report a mortality varying between 9,8 and 15%. Furthermore, postoperative mediastinitis is associated with prolonged hospital stay, an increased cost of care and a significant impairment in long-term survival.
Although a wide range of wound-healing strategies has been established, there is no general consensus regarding the appropriate surgical approach to mediastinitis following open-heart surgery.
Before 2003, the treatment of postoperative mediastinitis consisted of cooperation with a plastic surgeon, who performed a reconstruction with a vascularised soft tissue flap, followed by closing the defect with a split-skin graft. The flap used consisted of pectoral muscle flap, omentum or a combination of those two. The sternum remained open, thus was not fixated. Other treatment modalities used in this period were a closed irrigation system and open wound treatment.
After this period all postoperative mediastinitis patients were treated with Vacuum Assisted Closure therapy (VAC-therapy), followed by sternal closure and a reconstruction with a partial pectoral muscle flap and immediate closure of the soft tissue defect.
To decide which therapy is more successful every group will be retrospectively analyzed and compared.

We expect a better result for patients treated after 2003, because of the re-establishment of normal chest stability by closing the sternum. Therefore we expect a shorter time of treatment, a decline in morbidity and an improvement of the well-being of the patients

Study objective

The aim of this study is to compare the clinical outcome and survival in patients undergoing sternal closure treatment or conventional treatment for postoperative mediastinitis.
The secondary objective is to determine incidence of mediastinitis and risk factors for mediastinitis. Furthermore we will compare the subgroups of the conventional treatment group with the sternal closure group.

Study design

The design of the study is a retrospective, single-center analysis of medical records of patients diagnosed with postoperative mediastinitis. Follow-up will be done using two questionnaires.

Study burden and risks

Because consensus is not yet achieved regarding the best treatment of postoperative mediastinitis, it is important to ask about the patients' experiences and opinion. The result of the treatment is the most important outcome and the patient is the only one who can decide if it is acceptable or

not. The time burden is minimal: only 20-30 minutes in total. The emotional burden could be bigger, because the questionnaires focus on a difficult period. We also ask the patients about abilities they lost because of the treatment. On the other hand, this questionnaire could be a way for patients to expel their (dis)content.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
Nederland
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients diagnosed with postoperative mediastinitis receiving one of the following treatments:
- reconstruction with a vascularised soft tissue flap (omentum and/or pectoral muscle flap), followed by closure with a split-skin graft
- closed irrigation system

- open wound treatment
- VAC-therapy, followed by sternal closure and a reconstruction with a partial pectoral muscle flap and immediate closure of the soft tissue defect

Exclusion criteria

- all patients diagnosed with postoperative mediastinitis not receiving one of the above treatments (e.g. VAC-therapy only);- patients diagnosed with postoperative mediastinitis who died before receiving treatment

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL18611.058.07