Local gentamicin in Redon treated post-sternotomy mediastinitis

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The aim of our study is to evaluate clinical outcomes of patients primarily closed over Redon catheters for the treatment of PSM, comparing the application of local gentamicin with a control group.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON41174

Source
ToetsingOnline

Brief title
GentaTrial

Condition

- Bacterial infectious disorders
- Procedural related injuries and complications NEC
- Cardiac therapeutic procedures

Synonym
Post-sternotomy mediastintis, surgical site infection after cardiac surgery

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Local gentamicin, Post-sternotomy mediastinitis, Redon, Surgical site infection

Outcome measures

Primary outcome

Hospital stay

Secondary outcome

In-hospital mortality

Duration of wound sterilization

Duration of antibiotic treatment

Duration of drainage

CRP decline

Leukocyte decline

Study description

Background summary

Post-sternotomy mediastinitis (PSM) is a severe complication of open heart surgery with low incidence, but high mortality rates, up to 25%. Nowadays both VAC-therapy and Redon therapy are used to treat PSM. These treatment methods resulted in a decreased mortality rate of PSM till respectively 13% and 14% in the St. Antonius Hospital. In Redon treated PSM the sternum is closed primarily, leaving 2-8 drains in the infected area. No wound debridement and shorter length of treatment are the benefits of using this technique over VAC-therapy for the treatment of PSM.
To date just one study used local gentamicin in the treatment of PSM. In this study 42 mediastinitis patients were primarily closed over high suction Redon catheters, leaving gentamicin between the sternal halves. Mean duration of wound sterilization was 25.7 +- 8.6 hours. Duration of hospital stay was 14 +- 5.8 days. There was no mortality. Although this was a retrospective study, the results are very promising. Both duration of wound sterilization and hospital stay are significantly shorter compared with the results of Redon treated patients in St. Antonius and Amphia hospital, with a wound sterilization time

of approximately 26 days and a hospital stay of 33 days.

Study objective

The aim of our study is to evaluate clinical outcomes of patients primarily closed over Redon catheters for the treatment of PSM, comparing the application of local gentamicin with a control group.

Study design

Randomized controlled single blind trial

Intervention

Patients in the treatment group receive two collagenous drug carriers loaded with gentamicin between the sternal halves before closure. Patients in the control group are closed as usual.

Study burden and risks

Patients in the treatment group receive two collagenous drug carriers loaded with gentamicin. Risks of the application of this drug carrier are minimal. The drug carrier is approved for the Dutch market for this indication. The control group will receive standard treatment. There will be no extra physical examinations, no extra tests and no questionnaires or diaries. There is no physical or physiological discomfort associated with participation.

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

- Age above 18 years
- Underwent a cardiothoracic procedure through median sternotomy
- Clinical signs of PSM as described by the Centres for Disease Control and Prevention (CDC)

Exclusion criteria

- Patients with severe renal failure (serum creatinine above 150 µmol/L)
- Patients with neuromuscular diseases
- Patients who are allergic for aminoglycosides
- Patients with systemic lupus erythematosus, scleroderma or chronic polyarthritis

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Collatamp
Generic name:	Gentamicin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	17-09-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-01-2015
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
EudraCT	EUCTR2014-001170-33-NL
CCMO	NL48656.100.14