

GENTAmicin-collagen sponge reduces sternal wound complications after heart surgery

Submission date 19/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/01/2012	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
GENTAmicin-collagen sponge reduces sternal wound complications after heart surgery: a prospective, double-blind, randomised controlled study

Acronym

GENTA

Study objectives

Gentamicin-collagen sponge reduces sternal wound complications after heart surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Prospective double-blind randomised controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Sternal wound infection

Interventions

From June 2009 to June 2010, 723 out of 994 patients (72.7%) were enrolled (control group: n=369 versus intervention group: n=354). 723 consecutive cardiac surgery patients who underwent median sternotomy were assigned either to a control placebo-group (collagen sponge) or an intervention-group (gentamicin-collagen sponge). All patients received intravenous (i.v.) perioperative antibiotic prophylaxis.

All operations were performed on the heart and thoracic aorta via median sternotomy at the Clinic for Thoracic, Cardiac and Thoracic Vascular Surgery of Würzburg University Hospital.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Gentamicin-collagen sponge

Primary outcome(s)

Mediastinitis-occurrence of deep sternal wound (DSWI) infections within 30 days of index surgery (follow-up period)

Key secondary outcome(s)

Occurrence of superficial wound infections (SSWI) requiring treatment, as well as further clinical parameters, including revision, bleeding volume, and need for transfusions during the follow-up period.

Completion date

01/04/2011

Eligibility

Key inclusion criteria

1. Male and female legally competent patient, aged 18 years or older
2. Cardiac surgery undergoing median sternotomy
3. Ability to provide written informed consent
4. No preoperative signs of thoracic inflammation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Existing osteitis, immunosuppressive therapy, known hypersensitivity to aminoglycoside antibiotics
2. Concurrent immunological disease
3. Pregnancy or lactation
4. Participation in another clinical study
5. Inability to give consent to participate in the study
6. Refusal to participate in the study before and/or during the follow-up period

Date of first enrolment

01/03/2011

Date of final enrolment

01/04/2011

Locations

Countries of recruitment

Germany

Study participating centre
University Hospital of Würzburg
Wuerzburg
Germany
97074

Sponsor information

Organisation
University Hospital of Würzburg (Germany)

ROR
<https://ror.org/03pvr2g57>

Funder(s)

Funder type
Industry

Funder Name
Resorba Wound Care (Wundversorgung) GmbH & Co. KG (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2012		Yes	No