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GENTAmicin-collagen sponge reduces sternal wound complications after heart surgery

Submission date	Recruitment status	[_] Prospectively registered
19/02/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/01/2012	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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 intevenous (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