# GENTAmicin-collagen sponge reduces sternal wound complications after heart surgery

Submission date 19/02/2011	<b>Recruitment status</b> No longer recruiting		
Registration date 24/05/2011	<b>Overall study status</b> Completed		
Last Edited 10/01/2012	<b>Condition category</b> Infections and Infestations	I	

Prospectively registered

[] Protocol

[] Statistical analysis plan

[X] Results

Individual participant data

### Plain English summary of protocol

Not provided at time of registration

### **Contact information**

**Type(s)** Scientific

**Contact name** Prof Rainer Leyh

### **Contact details**

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### Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure

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

#### Secondary outcome measures

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.

### Overall study start date

01/03/2011

### **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

#### **Age group** Adult

Lower age limit

18 Years

**Sex** Both

# **Target number of participants** 800

### 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

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)

**Sponsor details** Department for Thoracic, Cardiac and Thoracic Vascular Surgery c/o Dr. Schimmer Oberdürrbacherstraße 6 Wuerzburg Germany 97074 Schimmer\_c@klinik.uni-wuerzburg.de

**Sponsor type** Hospital/treatment centre

### ROR

https://ror.org/03pvr2g57

### Funder(s)

Funder type Industry

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

### **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

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