

# Prospective randomised single-blind trial for application of GENTA-COLL resorb® for treatment of acute and chronic osteomyelitis

<b>Submission date</b> 11/09/2008	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/10/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 22/12/2010	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Gunther Hofmann

### Contact details

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Klinik fur Unfall-, Hand- und Wiederherstellungschirurgie  
Erlanger Allee 101  
Jena  
Germany  
07740

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

GENTA-COLL study

## Study objectives

Local application of GENTA-COLL resorb® reduces the amount of operative revisions in the treatment of acute and chronic osteomyelitis.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics committee of University Jena gave approval on the 15th February 2008 (ref: 2202-01/08)

## Study design

Prospective randomised single-blind two centre therapy-optimisation trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## 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

Acute and chronic osteomyelitis

## Interventions

Patients with acute or chronic osteomyelitis localised in the shaft of a long bone and randomised into the treatment arm undergo surgery and will be treated with GENTA-COLL resorb® which is a local antibiotic therapy. After a few days a surgical revision will be performed, if needed, and treatment with GENTA-COLL resorb® will be repeated. This procedure will be repeated until no clinical or microbiological signs of infection are present for a patient. The control group will not be treated with the local antibiotic therapy.

Please note that as of 22/12/2010 this record's status was changed to 'STOPPED' as recruitment of the required quantity of patients was not feasible.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Amount of operative revisions until reaching clinical infection free and complete germfree status. A follow-up phase of 1 year is planned with measures 1, 3, 6 and 52 weeks after hospital discharge.

**Secondary outcome measures**

1. Time to reach clinical infection free (defined as not irritated soft tissue and no fistula and C-reactive protein [CRP] and leukocytes in normal range) and complete germfree (defined as tissue samples taken during the operation and analysed according to standardised microbiological tests result to be germfree) status
2. Incidence of exacerbation of the infection/required amputation during the intervention phase (assessed before each new surgery)
3. Incidence of re-infections during the follow-up phase
4. Time between hospital discharge and incidence of re-infection

A follow-up phase of 1 year is planned with measures 1, 3, 6 and 52 weeks after hospital discharge.

**Overall study start date**

15/02/2008

**Completion date**

15/02/2011

**Reason abandoned (if study stopped)**

Lack of participants

**Eligibility****Key inclusion criteria**

1. Patients with acute and chronic osteomyelitis localised in the shaft of a long bone. Clinical and laboratory inflammation parameters must be present.
2. Aged greater than or equal to 18 years, either sex
3. Written informed consent of the patient

**Participant type(s)**

Patient

**Age group**

Not Specified

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

320

**Key exclusion criteria**

1. Joint infection and infiltration of osteomyelitis into the joint, respectively
2. Periprosthetic infection ("Endoprosthesis infection")
3. Osteomyelitis on two or more locations within a patient
4. Known microbiologically proven resistance against gentamicin
5. Vacuum sealing in revision-induced soft tissue defect; application of vacuum therapy (no continuous vacuum)
6. Known concomitant diseases, e.g. renal insufficiency, immunological diseases (among others autoimmune disease), neuromuscular disorders (among others Parkinson disease, Myasthenia gravis), connective tissue disease
7. Contraindication to the planned therapy (e.g. known hypersensitivity to collagen and/or gentamicin or other aminoglycoside antibiotics)
8. Expected low compliance
9. Pregnant or nursing women
10. Women with child bearing potency (less than 2 years after last menstruation) without effective contraception (i.e. implants, injectables, combined oral contraceptives, some intra-uterine devices [IUDs] or vasectomised partner) up to three weeks after end of treatment during the conduct of the trial
11. Concomitant participation in other clinical trials
12. Inability to consent to trial participation or to answer to needed information (e.g. organic psychosyndrome, dementia)
13. At least one of the following concomitant medication:
  - 13.1. Systemic administration of aminoglycoside antibiotics
  - 13.2. Loop diuretics (e.g. furosemide or ethacrynic acid), diuretics (intravenously [i.v.])
  - 13.3. Simultaneous or consecutive systemic or topical application of potentially neurotoxic and /or nephrotoxic substances, e.g. cisplatin, other aminoglycosides, streptomycin, cefaloridin, viomycin, polymyxin B or polymyxin E
  - 13.4. Local use of beta-lactam antibiotics
  - 13.5. Muscle relaxants (except for anaesthesia), e.g. d-tubocurarine, suxamethonium or pancuronium, ether

**Date of first enrolment**

15/02/2008

**Date of final enrolment**

15/02/2011

**Locations****Countries of recruitment**

Germany

**Study participating centre**

**Klinikum der Friedrich Schiller Universität Jena**  
Jena  
Germany  
07740

## **Sponsor information**

### **Organisation**

Friedrich Schiller University Jena (Friedrich-Schiller-Universität Jena) (Germany)

### **Sponsor details**

c/o Prof. Dr. med. Dr. rer. nat. Gunther Hofmann  
Klinik für Unfall-, Hand- und Wiederherstellungschirurgie  
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07740

### **Sponsor type**

University/education

### **Website**

<http://www.uniklinikum-jena.de/Willkommen.html>

### **ROR**

<https://ror.org/05qpz1x62>

## **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