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

Submission date
11/09/2008

Recruitment status
Stopped

Registration date
23/10/2008

Overall study status
Stopped

Last Edited
22/12/2010

Condition category
Musculoskeletal Diseases

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

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

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Not Specified

Lower age limit
18 years

Sex
All

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. cisplatinum, 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 Universitat Jena
Jena
Germany
07740

Sponsor information

Organisation
Friedrich Schiller University Jena (Friedrich-Schiller-Universitat Jena) (Germany)

ROR
https://ror.org/05qpz1x62

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