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# Comparision of bone-drilling techniques in the management of long bone infection following fracture repair by metal rod insertion

**Submission date**
23/07/2019

**Recruitment status**
No longer recruiting

**Registration date**
29/07/2019

**Overall study status**
Completed

**Last Edited**
10/01/2020

**Condition category**
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Treatment for fractures of long bones in the leg (femur and tibia) usually involves the insertion fo a metal rod into the bone cavity to provide additional strength and support (intermedullary nailing). In one to two percent of cases the bone cavity can become infected. Treating the infected area involves removal of the metal rod and drilling out (reaming) the infected bone. The aim of this study is to compare the postoperative effects of two methods of intermedullary reaming.

Who can participate?
Patients aged over 18 years diagnosed with an infection of the bone cavity previously treated by insertion of a metal rod into the bone.

What does the study involve?
Patients undergo surgical removal of the infected metal rod followed by either conventional reaming or reaming using the Reamer / Irrigator / Aspirator (RIA) system (Synthes, Inc. West Chester, Philadelphia, PA, USA). Patients then attended routine follow up visits to the hospital at 1, 3, 6, 12 and 24 months after the operation.

What are the possible benefits and risks of participating?
During the research, there is no direct benefit to the participant

Where is the study run from?
Federal University of São Paulo - Hospital São Paulo (UNIFESP)

When is the study starting and how long is it expected to run for?
August 2013 to July 2015

Who is funding the study?
Universidade Federal de São Paulo

Who is the main contact?
Mauro Salles
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
354.934

# Study information

### Scientific Title
The intramedullary reaming modality for the management of postoperative long bone infection: a prospective randomized controlled trial

### Study objectives
To compare the efficacy of reamer/irrigator/aspirator (RIA) with conventional reaming followed by insertion of antibiotic-loaded cement, for the treatment of intramedullary nail infection of long bones

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 16/08/2013, Research and Ethics Committee of the Federal University of São Paulo (UNIFESP) (Rua Botucatu, 572 1º Andar Conj. 14, Vila Clementino, Sao Paulo, Brazil; +55 115539-7162; cepunifesp@unifesp.br), ref: 354.934

## Study design
Prospective randomized controlled single-blinded clinical trial

## 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
Intramedullary nail infection

## Interventions
A noninferiority, randomized clinical trial was carried out involving patients of whom a locked IMN implant of the femur and/or tibia was retrieved and who all met the clinical and radiological criteria for IMN-associated osteomyelitis. Patients were randomized into two groups: RIA alone versus conventional reaming followed by antibiotic-loaded cement insertion. Both groups also underwent six-weeks of antibiotic treatment according to the results of the antibiogram. Patients were evaluated after 1, 3, 6, 12 and 24 months for radiological and clinical follow-up.

Consecutive patients with clinically suspected intramedullary infection who underwent nailing explantation and surgical debridement were randomised to receive either conventional reaming or reamer/irrigator/aspirator (RIA) of the presumed infected medullary canal.

Patients presenting intramedullary infection were assessed at the trauma unit and the outpatient setting by the infectious disease specialist and recruited after signed consent. Allocation of patients to the treatment groups took place at the time of anesthesia within the operative room. Then, randomization to conventional reaming or RIA was set up in a simple randomization procedure (1:1 ratio) with sealed opaque envelopes, sequentially numbered. The CONSORT guidelines were followed throughout the study.

## Intervention Type
Procedure/Surgery

## Primary outcome measure

Intramedullary infection two-year remission rate, performed using all randomized patients that completed at least one-year of follow-up in the per-protocol (PP) analysis. Patients were considered in remission when there was an absence of clinical, laboratory and radiological signs of infection, assessed in the last medical consultation (at least 12 months follow-up). Cases that did not require re-operation or further antibiotic administration for the same site of infection were also considered to be in remission.

### Secondary outcome measures
Preoperative and postoperative pain measured by the Visual Analog Scale (EVA) scale at baseline and 1, 3, 6, 12 and 24 months postoperatively

### Overall study start date
24/06/2013

### Completion date
30/03/2016

## Eligibility

### Key inclusion criteria
1. 18 years and over
2. Previous tibia or femur intramedullary locking nail fixation who met the definitive clinical and radiological diagnosis of osseous infection

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
46

### Total final enrolment
44

### Key exclusion criteria
1. Diaphyseal diameter < 10 mm
2. Previous infection of the affected bone and patients with HIV or chronic renal failure were excluded from the study

### Date of first enrolment
30/08/2013

**Date of final enrolment**
20/07/2015

# Locations

**Countries of recruitment**
Brazil

**Study participating centre**
**Federal University of São Paulo - Hospital São Paulo (UNIFESP)**
Rua Napoleão de Barros 715
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# Sponsor information

**Organisation**
Federal University Of São Paulo (UNIFESP)

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**Sponsor type**
University/education

**Website**
www.unifesp.br

**ROR**
https://ror.org/02k5swt12

# Funder(s)

**Funder type**
University/education

**Funder Name**
Universidade Federal de São Paulo

# Results and Publications

## Publication and dissemination plan
Planned publication in Patient Safety in Surgery Journal

## Intention to publish date
24/07/2019

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Carlos Augusto Finelli (email: c.finelli@cecot.com.br). The type of data is a complete Excel datasheet. The data is already available upon request and will become available for a long as necessary. Data will be shared upon reasonable request. The criteria access would be a simple email contact with the corresponding author, explaining the reasons for accessing the data. Additional analysis may also be requested upon reasonable rational. No further participants consent will be required including additional comments on data anonymization, as it has already been gathered and declared.

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 02/12/2019 | 10/01/2020 | Yes | No |