

Recurrence of chronic posttraumatic bone infection: Risk factors analysis

Submission date 18/05/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/05/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 13/11/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Osteomyelitis is the term for bone infections. It is a difficult to cure infection and despite improvements in treatment, there has still been a steady increase in its frequency, especially in adults. Osteomyelitis commonly occurs after some sort of trauma or injury such as a fall, self-harm and violence, or road traffic injuries. Posttraumatic osteomyelitis (PTO) is a microbial (bacteria or fungi) infection of a bone which may lead to bone destruction. It is usually results from any type of trauma or an infection from the surgical treatment of the trauma that allows organisms to enter bone and cause infection. Treatment of PTO requires surgery and the use of antibiotics. There are not a lot of studies focusing on the outcomes and predictors of treatment failure of bone infection following PTO treatment. Detailed studies that address predisposing factors to recurrence of PTO are important as they may help create efficient and cost saving control measures to reduce the frequency of recurrent PTO. The aim of this study is to determine the frequency of recurrence following treatment of PTO, and identify subjects, injury, pathogen, and surgery-associated risk factors predisposing patients to recurrence of PTO.

Who can participate?

Adults over the age of 12 with PTO.

What does the study involve?

Participants are asked to join this study if they present the diagnosis of PTO, have a complete medical record and are within a minimum of one year of follow up since their diagnosis. Researchers gather data about treatment failure (such as patient comorbidities (other illnesses), injury, microbiological findings, and surgery associated variables) as well as recurrence of infection from the participant's medical records.

What are the possible benefits and risks of participating?

There are no notable benefits or risks with participating.

Where is the study run from?

Fundação Faculdade Regional de Medicina S J Rio Preto (Brazil)

When is the study starting and how long is it expected to run for?
February 2007 to September 2013

Who is funding the study?
Investigator funded and initiated (Brazil)

Who is the main contact?
1. Dr Luciana Souza Jorge (Scientific)
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2. Prof Dr Mauro Jose Costa Salles (Scientific)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

234.654

Study information

Scientific Title

Predisposing factors for recurrence of chronic posttraumatic osteomyelitis: A retrospective observational cohort study from a tertiary referral center in Brazil.

Study objectives

The aim of this study is to identify subjects, injury, pathogen, and surgery-associated risk factors predisposing patients to recurrence of posttraumatic osteomyelitis (PTO).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board (Fundação Faculdade Regional de Medicina Sao Jose do Rio Preto), 09/04/2013, ref: protocol number: 234.654

Study design

Single-center retrospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Prevention

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

Chronic post-traumatic osteomyelitis

Interventions

This is a retrospective chart review study. The focus of the data collection is to compare characteristics of patients according to outcome, defined as treatment success and failure (recurrence) of PTO, and identify possible risk factors associated with recurrence. Patients who

developed PTO during the cohort study, and upon which the medical records are complete for analysis, are eligible for the study.

The data gathered from the medical records include treatment failure or recurrent infection was defined as infection at the same site that had been previously controlled and required re-operation and/or a second complete course of parenteral antibiotic therapy.

For the purpose of study analysis, only the first episode of recurrence are included and subsequent episodes are further excluded. In order to identify potential risk factors associated with failure of treatment of PTO, several variables (patient comorbidities, injury, microbiological findings, and surgery associated variables) are assessed by reviewing medical, intra-operative, and microbiological records. For statistical analysis, the follow-up is defined as the time interval between the date of the first medical visit and date of remission or failure of treatment of PTO, considering at least one-year of follow-up.

Intervention Type

Other

Primary outcome measure

Risk factors predisposing patients to recurrence of PTO (subjects, injury, pathogen, and surgery-associated) are measured using medical records within one year from diagnosis.

Secondary outcome measures

The frequency of recurrence following treatment of PTO is measured using medical records at first medical visit.

Overall study start date

01/02/2007

Completion date

01/09/2013

Eligibility

Key inclusion criteria

1. Older than 12 years of age
2. At least one year of follow-up after the surgical procedures
3. Diagnosed with chronic osteomyelitis
4. Complete medical records
5. Osteomyelitis was defined based upon the Center for Disease Control and Prevention (CDC) /National Healthcare Safety Network (NHSN) guidelines
6. Patients in remission of infection when there was absence of clinical, laboratory, or radiological signs of infection evaluated during the last medical visit (minimum of one year of follow-up), and in cases in which there was no need for reoperation or administration of an extra course of antibiotic therapy for the same site of infection following the end of therapy
7. Treatment failure or recurrent infection was defined as infection at the same site that had been previously controlled and required reoperation and/or a second complete course of parenteral antibiotic therapy

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

150 patients with posttraumatic osteomyelitis

Key exclusion criteria

1. Diagnosed with a previous history of infection at the same site
2. Incomplete medical records

Date of first enrolment

01/08/2007

Date of final enrolment

30/08/2012

Locations

Countries of recruitment

Brazil

Study participating centre

Fundação Faculdade Regional de Medicina S J Rio Preto

Avenida Brigadeiro Faria Lima 5544

Sao Jose do Rio Preto

Brazil

15090-000

Sponsor information

Organisation

Fundação Faculdade de Medicina de São José do Rio Preto

Sponsor details

Av Brigadeiro Faria Lima 5544

São José do Rio Preto

Brazil

15090000

Sponsor type

Hospital/treatment centre

Website

<http://www.famerp.br/novoportal/>

ROR

<https://ror.org/052e6h087>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

19/05/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Luciana Souza Jorge at lucianasjorge@gmail.com and Mauro José Costa Salles at salles.infecto@gmail.com.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/06/2017		Yes	No