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Recurrence of chronic posttraumatic bone infection: Risk factors analysis

Submission date
18/05/2017

Recruitment status
No longer recruiting

Registration date
18/05/2017

Overall study status
Completed

Last Edited
13/11/2017

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number

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

Study type(s)
Prevention

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

Key secondary outcome(s))
The frequency of recurrence following treatment of PTO is measured using medical records at first medical visit.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
Fundação Faculdade de Medicina de São José do Rio Preto

ROR
https://ror.org/052e6h087

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes