

Tibial open fractures fixation: intramedullary nailing versus bridge plating

Submission date 23/02/2012	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 12/03/2012	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 01/08/2014	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Open fractures of the tibia (shinbone) are very frequent and severe. The aim of this study is to compare two different operations, intramedullary nailing and bridge plating, for the treatment of open fractures of the tibia.

Who can participate?

Patients who suffer open fractures of the tibia.

What does the study involve?

Patients will be randomly allocated to undergo either the intramedullary nailing or the bridge plating operation.

What are the possible benefits and risks of participating?

By participating in the study the patient will benefit from thorough monitoring and unrestricted access to professionals involved in the study and it should be easy to treat possible complications that can occur. The risks to the patient are a result of the nature of this injury, in which the most common complications are infection and non-union (permanent failure of healing). Participation in the study adds no additional risk.

Where is the study run from?

The study will be performed at the Hospital São Paulo, Brazil.

When is the study starting and how long is it expected to run for?

The study started in August 2004 and was completed in September 2009.

Who is funding the study?

Universidade Federal de São Paulo (UNIFESP).

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Study information

Scientific Title

Tibial open fractures fixation - intramedullary nailing versus bridge plating: a randomized clinical trial

Study objectives

Intramedullary nail and bridge plating have similar results, but the bridge plating method has a lower cost.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Universidade Federal de São Paulo - Hospital São Paulo Ethics Committee, 10/12/2004, ref: CEP 1179/04 UNIFESP

Primary study design

Interventional

Study design

Randomized single-center clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Tibial open fracture

Interventions

Patients will be randomized to:

1. The intramedullary nail group:

Prophylactic antibiotics will be used at the emergency room, and the participants will be undergo the operation within eight hours after the injury. Under a anesthetic procedure (local or general), the patient will be positioned in a supine position. The involved leg will be prepared and draped, and an irrigation procedure with saline solution and debridement of devitalized soft tissues will be done at the fracture site. The fracture site will be reduced and fixed with a non-reamed locked intramedullary nail. The soft tissues will be closed or will be left open if tense. A cast will be used for comfort for 7 days, and then a physiotherapist will instruct the patient.

2. The bridge plating group:

The same preparation of nail group, but the fracture will be fixed with a narrow 4,5 DC-plate, usually with 12 to 16 holes. Two or three bicortical screws will be used in each side

Identical care program for rehabilitation will be done in each of compared groups. Following enrolment in the study, all the participants will be seen every week during the first month and at 3, 6 and 12 months and all primary and secondary outcomes will be reported.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Need of reoperation on months 3, 6, 9, or 12.

Key secondary outcome(s)

1. Non-union rate on months 6, 9 or 12
2. Infection rate
3. Mal-alignment rate on months 3, 6, 9 or 12
4. Functional score (Johner and Whrus) and life quality score (SF-36) on months 6 and 12

Completion date

16/09/2009

Eligibility

Key inclusion criteria

1. Patients of both sexes
2. Adults who have growth plate closed to radiographic examination
3. Open fractures of the tibial shaft with less than 8 hours of occurrence

The classification used in this study for the degree of exposure of the fracture is described by Gustilo and Anderson in 1976 and modified by Gustilo, Mendoza and Williams in 1984, and will be included fractures of type I, II and IIIA.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Presence of previous traumatic or infectious lesion in the fractured tibia
2. Associated lesions which makes impossible the execution of a method or evaluation and postoperative rehabilitation
3. Chronic disease or other physical or mental conditions that preclude monitoring
4. Refusal to consent

Date of first enrolment

20/08/2004

Date of final enrolment

16/09/2009

Locations**Countries of recruitment**

Brazil

Study participating centre

Federal University of Sao Paulo

Mairiporã, Sao Paulo

Brazil

07600-000

Sponsor information**Organisation**

Federal University of Sao Paulo (Brazil)

ROR

<https://ror.org/02k5swt12>

Funder(s)

Funder type

University/education

Funder Name

Federal University of São Paulo (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration