

# Tibial open fractures fixation: intramedullary nailing versus bridge plating

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/03/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 01/08/2014	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

Daniel Balbachevsky.  
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# Contact information

## Type(s)

Scientific

## Contact name

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# Additional identifiers

## Protocol serial number

N/A

# 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

## Study design

Randomized single-center clinical trial

## Primary study design

Interventional

## 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