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# Tibial open fractures fixation: intramedullary nailing versus bridge plating

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 23/02/2012 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 12/03/2012 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 01/08/2014 | Injury, Occupational Diseases, Poisoning | [ ] 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

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

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

## Secondary outcome measures

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

### Overall study start date
20/08/2004

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
80 participants

### 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)

### Sponsor details
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### Sponsor type
University/education

### Website
http://www.unifesp.br/

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

## Funder(s)

### Funder type
University/education

### Funder Name
Federal University of São Paulo (Brazil)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**
Not provided at time of registration