

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparing Two Treatment Methods For Fixation Of Closed Extra Articular Fractures Of 1/3 Distal Tibial Bone: Distal Lcp Fixation Vs Intramedullary Nailing

#### Protocol summary

##### Summary

Background: Locking Compression Plate (LCP) and intramedullary nailing (IMN) are two common methods of treatment for distal tibia fractures each having its advantages and disadvantages. The aim of the present study was to compare therapeutic results of these two methods on distal tibia fractures. Material and methods: Patients with closed extra-articular fractures of one third distal tibial bone were referred to Imam Reza and Kamyab hospitals, included in this study. Herein, a clinical trial on 64 patients (aged 18 to 70 years) was performed in period of one year with patients randomly assigned to one of the IMN or LCP group. After the surgical management of the fracture, the average time of surgery, average time for callus formation, time required for full weight bearing, the need for second surgery, and the occurrence of surgical complications such as infection, mal-alignment, delay in callus formation, and device failure, were compared between the two groups. Data were analyzed using a student's t-test and Chi square test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012081410596N1**  
Registration date: **2012-12-10, 1391/09/20**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-10, 1391/09/20

##### Registrant information

Name

Farshid Bagheri

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1852 0028

##### Email address

bagherif@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2011-08-27, 1390/06/05

##### Expected recruitment end date

2012-11-25, 1391/09/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing Two Treatment Methods For Fixation Of Closed Extra Articular Fractures Of 1/3 Distal Tibial Bone: Distal Lcp Fixation Vs Intramedullary Nailing

##### Public title

Comparing Two Treatment Methods For Fixation Of Closed Extra Articular Fractures Of 1/3 Distal leg Bone : Distal Lcp Fixation Vs Intramedullary Nailing

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with Closed Extra Articular Fractures Of 1/3 Distal Tibial Bone; male or female and

age between 18 to 70 years old. Exclusion criteria: patients who have underlying diseases like diabetes, hepatic failure, renal failure, neurologic, rheumatologic and cardiopulmonary or cancer diseases; patients who have open tibia fracture; patients with pathological fractures; patients with intra articular fractures; patients who are less than 18 and more than 70 years old and patients who have osteoporosis with any cause.

#### Age

From **18 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **64**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mashhad University of Medical Sciences

##### Street address

Ghoreishi Department, Vice chancellor for research,  
Mashhad University of Medical Sciences, University  
Street

##### City

mashhad

##### Postal code

#### Approval date

2011-08-27, 1390/06/05

#### Ethics committee reference number

900056

## Health conditions studied

### 1

#### Description of health condition studied

Closed Extra Articular Fractures Of 1/3 Distal Tibial Bone

#### ICD-10 code

S82.3

#### ICD-10 code description

Fracture of lower end of tibia

## Primary outcomes

### 1

#### Description

time of union

#### Timepoint

2 weekly for one month and monthly for 5 months

#### Method of measurement

radiology

### 2

#### Description

time of surgery

#### Timepoint

time from beginning to end of surgery

#### Method of measurement

minute

### 3

#### Description

time of weighting on foots

#### Timepoint

two weekly for one month and monthly for five months

#### Method of measurement

radiology and clinical examination

## Secondary outcomes

### 1

#### Description

infection

#### Timepoint

Weekly

#### Method of measurement

visit-measurement of ESR & CRP

## Intervention groups

### 1

#### Description

internal medullary nailing in intervention group

#### Category

Treatment - Surgery

### 2

#### Description

lcp plate in control group

#### Category

Treatment - Surgery

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Shahid Kamyab hospital

**Full name of responsible person**

**Street address**

**City**

Mashhad

## 2

### Recruitment center

**Name of recruitment center**

Imam Reza hospital

**Full name of responsible person**

**Street address**

**City**

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Ghoerishi Dpartment, Vice chancellor for research,  
Mashhad University of Medical Sciences, University  
Street, Mashhad

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Shahid Kamyab Hospital

**Full name of responsible person**

Dr Farshid Bagheri

**Position**

Assistant professor- member of faculty

### Other areas of specialty/work

**Street address**

Mashhad

**City**

Mashhad

**Postal code**

**Phone**

+98 51 1852 0028

**Fax**

**Email**

bagherif@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Farshid Bagheri

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Mashhad

**City**

Mashhad

**Postal code**

**Phone**

+98 51 1852 0028

**Fax**

**Email**

bagherif@mums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

mashhad university medical of sciences

**Full name of responsible person**

Dr Farshid Bagheri

**Position**

assistant professor

**Other areas of specialty/work**

**Street address**

**City**

mashhad

**Postal code**

**Phone**

**Fax**

**Email**

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*