

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

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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
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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

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Person responsible for scientific inquiries

Contact

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Assistant professor

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Position

assistant professor

Other areas of specialty/work**Street address****City**

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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