

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

External fixation compared with medullary nailing in tibia open fracture

Protocol summary

Summary

This randomized controlled clinical trial study was performed on 113 patients referred to Sari Imam Khomeini hospital in 1387-88 because of type I and II tibia open fracture according to Gastillo Criteria and underwent medullary nailing and external fixation surgery. After taking informed consent for participation in this trial, patients were divided in two groups randomly. Group A were operated by AO external fixation and group B by internal medullary nailing that were made in U.S.A. Intra venous prophylactic antibiotic therapy was used for 5days in accordance with infections disease specialists' advice and then if the wound condition was good, the patient was discharged. Evaluations after surgery included assessment regarding union, delayed union, non Union and infection. Patients followed weekly for the first month and then monthly during the 6 months after surgery until the union were achieved. At each visit a questionnaire were filled regarding the side effects. The patients were frequency matched according to sex, age and cause of trauma and type of fracture in three groups and were allocated to the three surgeons who were performing the operations. At each visit the patients underwent physical exam and a tibia radiography was done for each patient to identify union. The results were compared in the intervention and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809102798N1**

Registration date: **2010-10-05, 1389/07/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-05, 1389/07/13

Registrant information

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Masoud Shayestehazar

Name of organization / entity

Mazandaran University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandarn University of Medical Sciences

Expected recruitment start date

2008-10-22, 1387/08/01

Expected recruitment end date

2009-12-12, 1388/09/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

External fixation compared with medullary nailing in tibia open fracture

Public title

External fixation compared with medullary nailing, two techniques of operation in leg open fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with type I and II open tibial fracture. Exclusion criteria: Patients who have underlying diseases like diabetes, hepatic failure, renal failure, Neurologic, rheumatologic and cardiopulmonary diseases, immunocompromised patients, patients

arriving at hospital with more than 24 hours delay, patients who have received corticosteroids or are under chemotherapy, patients who are less than 18 and more than 50 years old and patients who have osteoporosis with any cause

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **113**

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**

Mazandarn University of Medical Sciences

Street address

Sari

City

Sari

Postal code**Approval date**

2009-08-25, 1388/06/03

Ethics committee reference number

88-85

Health conditions studied**1****Description of health condition studied**

open tibia fracture

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

Primary outcomes**1****Description**

union

Timepoint

weekly for one month and monthly for six month

Method of measurement

radiography

Secondary outcomes**1****Description**

complication

Timepoint

weekly for one month and monthly for six month

Method of measurement

radiography

Intervention groups**1****Description**

internal medullary nailing in intervention group

Category

Treatment - Devices

2**Description**

standard external fixation in control group

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Hospital of Sari

Full name of responsible person

Masoud Shayestehazar

Street address**City**

Sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmadali Enayati

Street address

Vice-chancellor of Research and Technology of
Mazandarn University of Medical Sciences

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University Of Medical Sciences

Full name of responsible person

Masoud Shayestehazar

Position

Associate Professor

Other areas of specialty/work

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Position

Associate professor

Other areas of specialty/work

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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