

# 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

##### Name

Masoud Shayestehazar

##### Name of organization / entity

Mazandaran University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1325 7230

##### Email address

mshayestehazar@mazums.ac.ir

#### 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**

**Street address**

Emam hospital of Sari

**City**

Sari

**Postal code**

**Phone**

+98 15 1326 1245

**Fax**

**Email**

Mshayestehazar@mazums.ac.ir

**Web page address**

**Person responsible for updating data**

**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**

**Street address**

**City**

Sari

**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*