

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Comparison of close versus open interlocking medulary nailing in fixation of femoral shaft fracture in adult

#### Protocol summary

##### Summary

Femoral shaft fracture is one of the major causes of mortality and morbidity. Antigrade femoral interlocking nailing is the standard treatment of femoral shaft fractures in adults. In this study the results of open and closed nailing in femoral shaft fractures are compared. This clinical trial study is performed on 40 patients with closed traumatic femoral shaft fracture without any systemic or metabolic disease. femoral shaft fracture, for the control group patients will be managed with open reduction technique whereas, for the case group patients, it is managed with closed reduction technique performed at the first week after the patients admission to the hospital. All patients will be followed up for minimum one year after surgery and primary outcomes including the union time of fracture and infection rate will be compared between case and control groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203129272N1**

Registration date: **2012-09-22, 1391/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-09-22, 1391/07/01

##### Registrant information

##### Name

Javad Khajemozafari

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 1223 0230

##### Email address

mozafari@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2009-03-21, 1388/01/01

##### Expected recruitment end date

2010-03-20, 1388/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of close versus open interlocking medulary nailing in fixation of femoral shaft fracture in adult

##### Public title

open and close treatment of femoral shaft fracture

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: closed femoral shaft fracture; traumatic fracture; without any systemic or metabolic disease  
exclusion criteria: open fracture; pathologic fracture: multiple fracture; head trauma; viseral injury; systemic or metabolic disease

##### Age

From **18 years** old to **50 years** old

##### Gender

Both

##### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 40

## 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

Central building of University, Daneshgah str.,  
Mashhad

##### City

Mashhad

##### Postal code

#### Approval date

2009-03-03, 1387/12/13

#### Ethics committee reference number

1978138

## Health conditions studied

### 1

#### Description of health condition studied

Femor fracture

#### ICD-10 code

S72.3

#### ICD-10 code description

Fracture of shaft of femur

## Primary outcomes

### 1

#### Description

Union

#### Timepoint

befor surgery, 2-4-6-8-12-16-20-24 week after surgery

#### Method of measurement

Radiography, Clinical examination

### 2

#### Description

osteomyelitis

#### Timepoint

befor surgery, 4-8-12-16 week after surgery

#### Method of measurement

pusy discharge in clinical examination, ESR, CRP

## Secondary outcomes

### 1

#### Description

Soft callus formation

#### Timepoint

after surgery in 2, 4, 6, 8, 12 weekly

#### Method of measurement

Radiography

### 2

#### Description

Full Weight Bearing

#### Timepoint

after surgery: 2, 4, 6, 8, 12, 16, 20, 24 week

#### Method of measurement

observation

### 3

#### Description

blood transfusion

#### Timepoint

intra operation and during 2 week after surgery

#### Method of measurement

milliliter

### 4

#### Description

X ray

#### Timepoint

intraoperative

#### Method of measurement

shot

## Intervention groups

### 1

#### Description

Intervention: Closed reduction of fracture

#### Category

Treatment - Surgery

### 2

#### Description

control: open reduction of fracture

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Kamyab Hospital

**Full name of responsible person**

Javad Khajemozafari Dr.

**Street address**

Fadaieyan Eslam Avenue, Nakhrisi Square, Mashhad

**City**

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Peivandi MT.

**Street address**

Fadaieyan Eslam Avenue, Nakhrisi Square, 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Javad Khajemozafari

**Position**

Assistant professor of orthopaedic

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

Fadaieyan Eslam Avenue, Nakhrisi Square, Mashhad

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+98 51 1859 6606

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mozafari75@yahoo.com

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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Peivandi MT

**Position**

Assosieited Professor

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Shahid Kamyab Hospital, Fadaieyan Eslam Avenue, Nakhrisi Square, Mashhad

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant professor

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## 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*