

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)

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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; visceral 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

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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

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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

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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