

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigation and comparison of the treatment of non-union fractures of the femur by two methods of nail exchange and the use of bone grafting along with plate augmentation.

Protocol summary

Study aim

Determining and comparing the treatment of non-union fractures of the femur by two methods of nail exchange and the use of plate augmentation

Design

This study will be conducted in the form of a clinical trial with a control group with two randomized parallel groups and without blinding on 40 patients among the population of patients with non-union femur fractures. Patients will be randomly assigned to one of the study groups. A table of random numbers will be used for randomization.

Settings and conduct

This study will be conducted in the city of Isfahan in 2023 as a clinical trial in the population of patients with non-union femur fracture. After randomization, patients will be divided into one of two study groups. Blinding was not done. The first group will be treated with intermedullary nailing and the second group will be treated with plate augmentation.

Participants/Inclusion and exclusion criteria

1. Patients with transverse and oblique fractures (the fracture line with the axis of the femoral medulla has an angle of less than 45 degrees) femur treated with intra-medullary nail; 2. Diagnosis of non-union by an orthopedic specialist 6 months after surgery; 3. Candidate for surgery to correct non-union; 4. Informed consent.

Intervention groups

All patients will be placed in two groups. The first group will be treated with intermedullary nailing and the second group will be treated with plate augmentation

Main outcome variables

Bony union

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230211057388N1**

Registration date: **2023-03-05, 1401/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-05, 1401/12/14**

Update count: **0**

Registration date

2023-03-05, 1401/12/14

Registrant information

Name

Mohammad Shahsavan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8672 5503

Email address

mohammad1443shah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation and comparison of the treatment of non-union fractures of the femur by two methods of nail exchange and the use of bone grafting along with plate augmentation.

Public title

Non-union femoral shaft fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with transverse and oblique fractures (the fracture line with the axis of the femoral medulla has an angle of less than 45 degrees) femur treated with intra-medullary nail Diagnosis of non-union by orthopedic specialist 6 months after surgery A candidate for surgery to correct non-union Informed consent

Exclusion criteria:

Underlying disease Infectious nonunion Re-fracture

Age

From **18 years** old to **60 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

randomization will be done with the help of random number table. If the number is even, it will belong to the first group, and if it is odd, it will belong to the second group.

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

Ethics committee of isfahan university of medical science

Street address

Hezar jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-11-08, 1400/08/17

Ethics committee reference number

IR.MUI.MED.REC.1400.624

Health conditions studied

1

Description of health condition studied

Femoral fracture non union

ICD-10 code

S72.3

ICD-10 code description

Fracture of shaft of femur

Primary outcomes

1

Description

Bony union

Timepoint

3 and 6 months postoperatively

Method of measurement

Medical history, physical exam, radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intramedullary nailing. The intramedullary canal will be over-reamed several sizes, and a nail at least 1 mm (ranging from 1 to 3 mm) larger in diameter will be inserted. The average initial nail diameter.

Category

Treatment - Devices

2

Description

Intervention group: plate augmentation. An augmentation plate with autogenous bone grafting will be performed after exposing the nonunion site using the lateral approach. Cortico-cancellous bone grafts from ipsilateral iliac crest will be harvested simultaneously by another surgical team. We will use dynamic compression plates (DCP) with eight holes

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Mohammad Shahsavan

Street address

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City

Isfahan

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Email

mohammad_shah69@res.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjooy

Street address

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vcr-office@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Shahsavan

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available