

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of the results of treatment of pilon fracture with low profile plate

Protocol summary

Study aim

Evaluation of the results of treatment of pilon fracture with low profile plate

Design

Clinical trial without control group, phase 3 on 40patients

Settings and conduct

This study is performed in Kashani Hospital in Isfahan. Patients are evaluated at one-month, three-month, and six-month intervals. Examination for superficial wound infections, evidence of osteomyelitis, non-healing and bad welding are evaluated in two axes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pilon fracture based on specialist diagnosis, patient consent to participate in the study, unilateral fracture. Exclusion criteria: open fracture, soft tissue injury, history of previous fracture or deformity in the ankle, history of systemic disease such as diabetes

Intervention groups

Intervention group: Patients with pylon fractures will be treated with low profile plaques according to the inclusion and exclusion criteria. These patients are evaluated at intervals of one month, three months and six months. Examination for superficial wound infections, evidence of osteomyelitis, non-healing and bad welding are evaluated in two axes.

Main outcome variables

Superficial wound infections, evidence of osteomyelitis, non-union and malunion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046523N8**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **prospective**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Aryan Rafiee Zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 83 3837 1582

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rafieezadeh.a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the results of treatment of pilon fracture with low profile plate

Public title

Treatment of pilon fracture with low profile plate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pilon fracture based on specialist diagnosis Patient

consent to participate in the study Unilateral fracture
Exclusion criteria:
Open fracture Soft tissue damage History of previous ankle fracture or deformity History of systemic diseases such as diabetes

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-08-23, 1399/06/02

Ethics committee reference number

IR.MUI.MED.REC.1399.429

Health conditions studied

1

Description of health condition studied

Pilon fracture

ICD-10 code

S82.87

ICD-10 code description

Pilon fracture of tibia

Primary outcomes

1

Description

Superficial wound infections

Timepoint

With an interval of one month, three months and six months after surgery

Method of measurement

Visiting patients

2

Description

Evidence of osteomyelitis

Timepoint

With an interval of one month, three months and six months after surgery

Method of measurement

Visiting patients

3

Description

Non-union and malunion

Timepoint

With an interval of one month, three months and six months after surgery

Method of measurement

Examination and radiograph

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with pylon fractures will be treated with low profile plaques according to the inclusion and exclusion criteria. These patients are evaluated at intervals of one month, three months and six months. Examination for superficial wound infections, evidence of osteomyelitis, non-healing and bad welding are evaluated in two axes.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Ali Andalib
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No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan
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Email
haghjoo.sh@med.mui.ac.ir
Web page address
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

Ali Andalib
Position
Associate professor
Latest degree
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Other areas of specialty/work
Orthopedics
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Person responsible for updating data

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Email

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

What processes are involved for a request to access data/document

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments