Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Aryan Rafiee Zadeh
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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 IsfahanUniversity of Medical Sciences

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

City
Isfahan

Province
Isfehan

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
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Isfahan University of Medical Sciences, Hezar Jarib Ave,. Daneshgah Blvd, Isfahan
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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
Subspecialist
Other areas of specialty/work
Orthopedics
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Person responsible for updating data

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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