

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the minimally invasive surgical treatment outcomes of itra-extra articular calcaneal fracture's and non operative treatment in valiasr hospital

Protocol summary

Summary

This study was to compare the surgical outcomes of calcaneal fracture management between the open reduction and internal fixation technique (ORIF) and the MIS technique. In this randomized clinical trial, forty patients with calcaneus fractures were randomly assigned to two equal groups; ORIF group and MIS group. Patients were followed for 1 year post-operatively. Gissane and Bohler's angles, AOFAS questionnaire, pain intensity, ability to conduct previous activities and various complications like wound healing complications and irritation with shoe wear were assessed in the final post-operative visit. Eventually data obtained from the two groups were compared. Inclusion criteria: fracture type II and III Sanders Exclusion criteria: presence of fractures especially at the foot of the same side; bilateral calcaneous fracture; multiple fractures; open fracture; Diabetes; Rheumatoid Arthritis; patients under the age of 15; fractures that occurred more than three weeks after it occurred.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092720258N62**
Registration date: **2017-10-29, 1396/08/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-29, 1396/08/07

Registrant information

Name

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Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor and Research, Arak University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the minimally invasive surgical treatment outcomes of itra-extra articular calcaneal fracture's and non operative treatment in valiasr hospital

Public title

Comparison of the minimally invasive surgical treatment outcomes of itra-extra articular calcaneal fracture's and non operative treatment in valiasr hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: fracture type II and III Sanders

Exclusion criteria: presence of fractures especially at the

foot of the same side; bilateral calcaneus fracture; multiple fractures; open fracture; Diabetes; Rheumatoid Arthritis; patients under the age of 15; fractures that occurred more than three weeks after it occurred

Age

No age limit

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)**

Double 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 Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Postal code

38149578558

Approval date

2016-06-14, 1395/03/25

Ethics committee reference number

IR.ARAKMU.REC.1395.96

Health conditions studied**1****Description of health condition studied**

Calcaneus fracture

ICD-10 code

S92.0

ICD-10 code description

Fracture of calcaneus

Primary outcomes**1****Description**

Gissane and Bohler's angles

Timepoint

After 1 years surgery

Method of measurement

Degree

2**Description**

Functional level

Timepoint

After 1 years surgery

Method of measurement

AOFAS questionnaire

3**Description**

Pain

Timepoint

After 1 years surgery

Method of measurement

Visual Analogue Scale Questionnaire

4**Description**

Conduct previous activities

Timepoint

After 1 years surgery

Method of measurement

Observation

5**Description**

Various complications like wound healing complications

Timepoint

After 1 years surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This patient is surgery with open surgery.

Category

Treatment - Drugs

2

Description

Control group: patients treat with routin treatment.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Alireza Amani

Street address

Valiasr Hospital, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Dr Anoshirvani

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Arak

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Arak 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

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Full name of responsible person

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Position

Faculty member

Other areas of specialty/work

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Person responsible for updating data

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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