

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison between conventional and minimally invasive technique for treatment of calcaneal fracture.

Protocol summary

Summary

Objective: Comparison between conventional and minimally invasive techniques for treatment of calcaneal fracture. Design: 36 patients with calcaneal fracture admitted in Shahid Kamyab hospital will randomly divide into two groups using randomization table software. Participants: Patients with calcaneous fractures aged between 18 and 75 years excluding patients with open fracture. Intervention: In the first group 18 patients will operate using conventional large L type incision on the lateral surface of the ankle and in the second group the surgery on 18 patients will perform using 3 centimeters incision on the sinus tarsi region. Primary outcomes: Accuracy of reduction detected by measurement of Bohler and Gissane angles on the lateral radiography of the ankle and reduction of the articular surface on the coronal CT scan of the ankle; Functional assessment using VAS, AOFAS and SF36 questionnaires 6 and 12 months after the surgery; Rate of wound infection and dehiscence. Secondary outcomes: Rate of malunion and non-union of the fracture that will detect on plain radiographs and ankle CT scan.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051327872N1**

Registration date: **2017-07-17, 1396/04/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-17, 1396/04/26

Registrant information

Name

Sayyed Hadi Sayyed Hosseini

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 2121

Email address

hoseinih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between conventional and minimally invasive technique for treatment of calcaneal fracture.

Public title

Comparison of two surgical techniques for treatment of calcaneal fracture.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: calcaneal close fracture; age more than 18 years and less than 75 years, exclusion criteria: open calcaneal fracture; no indication for surgical treatment; uncontrolled systemic diseases; simultaneous foot fracture

Age

From **17 years** old to **74 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

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

Mashhad University of Medical Sciences, Research
Deputy, Committee of Ethics

Street address

Ghoreshi building, Daneshgah street, Mashhad, Iran

City

Mashhad

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.MUMS.REC.1396.34

Health conditions studied

1

Description of health condition studied

Calcaneos fracture

ICD-10 code

S92.0

ICD-10 code description

Fracture of calcaneus

Primary outcomes

1

Description

AOFAS score

Timepoint

6 months and one year later

Method of measurement

Filling the questionnaire

2

Description

Wound dehiscence

Timepoint

During three weeks after the surgery

Method of measurement

Visit the surgical wound

3

Description

Wound infection

Timepoint

During 3 weeks after the surgery

Method of measurement

Purulent discharge and culture of discharge

4

Description

VAS scorer

Timepoint

6 months and one year after the surgery

Method of measurement

Filling the questionnaire

5

Description

SF36

Timepoint

6 months and one year after the surgery

Method of measurement

Filling the questionnaire

6

Description

Accuracy of reduction

Timepoint

The day after surgery and one year later

Method of measurement

Measurement of the Bohler's and Gissane angles on
lateral radiograph and articular surface reduction on
coronal CT scan of the ankle

Secondary outcomes

1

Description

Non-union

Timepoint

6 months and one year after the surgery

Method of measurement

On the plain radiographs and CT scan of the ankle

2

Description

Malunion

Timepoint

6 months and one year after the surgery

Method of measurement

Using plane radiographs and CT scan of the ankle

Intervention groups

1

Description

In the intervention group calcaneal fracture will operate through the minimally invasive approach by using a 3 centimeter incision on sinus tarsi. After exposing the articular surface by removing the adipose tissue and retracting the extensor digitorum brevis muscle, reduction of the fracture will be done and primarily fixed by a pin and then by a screw the fracture will finally fix with a small plate.

Category

Treatment - Surgery

2

Description

In the control group the surgery will be performed using a large L type incision on the lateral aspect of the ankle and soft tissues including peroneal tendons will subperiosteally retract anteriorly the fracture and articular surface will be exposed and the reduction of the articular surface will be obtained and fixed by a screw and then the fracture will be fixed with a large calcaneal plate.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Kamyab Hospital

Full name of responsible person

Dr Sayyed Hadi Sayyed Hosseini

Street address

Nakhrisi junction, Fadayian Eslam Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Ghoreshi building, Daneshgah street, Mashhad, Iran

City

Mashhad

Grant name

Grant code / Reference number

950364

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

Dr Sayyed Hadi Sayyed Hosseini

Position

Assistant Professor of Orthopedics

Other areas of specialty/work

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Person responsible for scientific inquiries

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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