

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the results of tibia intercondylar eminence fracture fixation between headed and headless screws

Protocol summary

Study aim

Comparison of Fixation outcome of Intercondylar Fracture of Tibia Aminens between Sardar and Headless Screws

Design

The clinical trial with control group without blinding, phase 3 will be performed on 80 patients with intercondylar eminence fracture of the tibia. Patients will be randomly assigned to two parallel groups of 40 using the Excel Rand function. In one group, the intercondylar eminence fracture of tibia will be fixed with headed screw. In the other group, a headless screw will be used to fix the intercondylar eminence fracture of the tibia.

Settings and conduct

This study will be performed on patients with intercondylar eminence fracture of tibia referred to Besat Hospital in Hamadan. no blinding will be done in this study

Participants/Inclusion and exclusion criteria

Participants in this study are patients with intercondylar fracture of the tibia. Patients with meniscus and ligament injuries with fractures will not be included in the study

Intervention groups

The first group intercondylar fracture will be fixed with headed screw. The second intervention group intercondylar fracture will be fixed with headless screw.

Main outcome variables

Fracture union, Leg function including: need or lack of support when standing and bearing weight, ability to climb stairs, ability to gradually bend the knee in a standing position, stability and instability of the knee, swelling and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N22**

Registration date: **2022-04-18, 1401/01/29**

Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **0**

Registration date

2022-04-18, 1401/01/29

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the results of tibia intercondylar eminence fracture fixation between headed and headless screws

Public title

Methods for tibia intercondylar eminence fracture

fixation between headed

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Intracondylar fracture of the tibia

Exclusion criteria:

Comorbidity of meniscus and ligament damage

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are randomly divided into two groups. 20 balls will be thrown in an opaque bag, which includes 10 white balls and 10 black balls. With each patient, a ball is accidentally removed from the bag. If the color of the ball is white, Herbert screw will be used and if it is black, the cannula screw will be used. After each selection, the ball is returned to the bag

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 Hamadan University of Medical Science

Street address

shahid fahmideh

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Province

Hamadan

Postal code

6517838697

Approval date

2022-04-09, 1401/01/20

Ethics committee reference number

IR.UMSHA.REC.1401.031

Health conditions studied

1

Description of health condition studied

tibia intercondylar eminence fracture

ICD-10 code

542.4

ICD-10 code description

Fracture of lower end of humerus

Primary outcomes

1

Description

Fracture union, leg function (no limping, no need for support while standing and bearing weight, ability to climb stairs, ability to gradually bend the knee in a standing position, stability and instability of the knee, swelling and pain)

Timepoint

Patients will be evaluated at three time intervals of weeks 4, 8 and 12 after treatment

Method of measurement

Union with radiography and leg function will be assessed with the Lysholm knee scale questionnaire. This questionnaire measures limping, the need for support while standing and bearing weight, the ability to climb stairs, the ability to gradually bend the knee in a standing position, knee stability and instability, swelling and pain.

2

Description

Fracture union

Timepoint

Patients will be evaluated at three time intervals of weeks 4, 8 and 12 after treatment

Method of measurement

Radiography of the fracture site

Secondary outcomes

1

Description

Infection and abscess at the surgical site

Timepoint

The first and second weeks after surgery

Method of measurement

Clinical examination of the patient and observation of the surgical site

Intervention groups

1

Description

Intervention group: Fracture fixation with Sardar Herbert

screw

Category

Treatment - Devices

2

Description

Control group: Fracture fixation with headless screw cannula

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Gholamreza Ghorbani Amjad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available