

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of two methods of fixing lateral tibial plateau fractures (Schatzker type II and III) using 3.5 T plate and 4.5 low profile plate

Protocol summary

Study aim

Comparison of two methods of fixing lateral tibial plateau fractures (Schatzker type II and III) using 3.5 T plate and 4.5 low profile plate

Design

This is a clinical trial without a control group, with two parallel groups, open-label, non-randomized, on 80 patients.

Settings and conduct

This study is conducted in Ayatollah Kashani hospital in Isfahan city. Patients with lateral tibial plateau fractures (Schatzker type II and III) were included in the study based on the inclusion criteria and obtaining informed consent and will be treated non-randomly (based on clinical criteria and the specialist's decision) with one of two types of 3.5mm T-plate or 4.5mm low profile plate. Finally, the process of response to treatment 3 months, 6 months, and 12 months after the operation will be compared by examining the recovery time.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20 to 65 years, lateral tibial plateau fractures of schatzker type II and III, and confirming informed consent. Exclusion criteria: Patients with multiple traumas, open fractures, and pathologic fractures, and previous knee surgery.

Intervention groups

Intervention group 1: Patients who are candidates for surgery due to schatzker type II and III of tibial plateau fractures and undergo fixation with a 3.5mm T-plate. Intervention group 2: Patients who are candidates for surgery due to schatzker type II and III of tibial plateau fractures and undergo fixation with a 4.5mm low profile plate.

Main outcome variables

Recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051574N16**

Registration date: **2023-01-09, 1401/10/19**

Registration timing: **prospective**

Last update: **2023-01-09, 1401/10/19**

Update count: **0**

Registration date

2023-01-09, 1401/10/19

Registrant information

Name

Ghasem Mohammadsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 4005

Email address

mohammadsharifi.ghasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-17, 1401/10/27

Expected recruitment end date

2023-03-15, 1401/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of fixing lateral tibial plateau fractures (Schatzker type II and III) using 3.5 T plate and 4.5 low profile plate

Public title

Comparison of fixing lateral tibial plateau fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20 to 65 years Lateral tibial plateau fractures of schatzker type II and III Confirming informed consent

Exclusion criteria:

Patients with multiple traumas, open fractures, and pathologic fractures Previous knee surgery

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Esfahan University of Medical Sciences

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

IR.MUI.MED.REC.1400.609

Health conditions studied

1

Description of health condition studied

Tibial plateau fracture

ICD-10 code

S82.12

ICD-10 code description

Fracture of lateral condyle of tibia

Primary outcomes

1

Description

Recovery time

Timepoint

3, 6, and 12 months after surgery.

Method of measurement

Radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients who are candidates for surgery due to schatzker type II and III of tibial plateau fractures and undergo fixation with a 3.5mm T-plate.

Category

Treatment - Devices

2

Description

Intervention group 2: Patients who are candidates for surgery due to schatzker type II and III of tibial plateau fractures and undergo fixation with a 4.5mm low profile plate.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Ali sherafati-chalesshtori

Street address

Kashani St., Isfahan

City

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
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haghjoo.sh@med.mui.ac.ir

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
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Specialist
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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

Send a message to the mentioned e-mail address

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

E-mail the responsible person and if you accept the conditions, the information will be sent.

Comments