

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the treatment effects of hybrid and double plate surgery in tibial plateau fractures

Protocol summary

Summary

Objective: To assess the Union and nonUnion and the infection and rate of return to work in compared with double-plate hybrid therapy in tibial plateau comminuted fracture. design and setting: The study was based on clinical trial to compare the Union number (40) of 20 samples and 20 samples of hybrid double-plate treatment in patients with tibial plateau fractures in the study were split. major inclusion and exclusion: Patients with open fractures and closed tibial plateau comminuted fracture in the study of random pattern based on the hybrid method (external fixator plate on the medial and lateral) and double-plate treatment methods are fixed so that in cases with large pieces comminuted tibial plateau of double-plate and in the case of a hybrid method in the medial and lateral plate is placed external fixator used. intervention: intervention Groups: Fixation of tibial plateau fractures with medial and lateral plate. Contro group: tibial plateau fracture fixation with anatomical plate lateral and medial external fixator antero media.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507062798N5**

Registration date: **2015-12-24, 1394/10/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-24, 1394/10/03

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Mazandaran University Of Medical Science

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the treatment effects of hybrid and double plate surgery in tibial plateau fractures

Public title

Comparing the treatment effects of hybrid and double plate surgery in tibial plateau fractures

Purpose

Treatment

Inclusion/Exclusion criteria

exclude critria: Patients with underlying disease; diabetes; immunodeficiency and disease development are excluded. Patients with open fractures and closed tibial plateau comminuted fracture in the study of random pattern based on the hybrid method (external fixator plate on the medial and lateral) and double-plate treatment methods are fixed.

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)

N/A

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 Mazandaran University Of
Medical Science

Street address

Sari, Mazandaran

City

Sari

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

IR.MAZUMS.REC.94-1622

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

tibial plateaue fracture

ICD-10 code

S82.1

ICD-10 code description

Fracture of upper end of tibia

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

pain of the fracture site

Timepoint

2 week / month / two months / 6 months / year / two
years

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Union

Timepoint

2 months later, 6 months later

Method of measurement

Radiology

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

intervention Groups: Fixation of tibial plateau fractures
with medial and lateral plate

Category

Diagnosis

2**Description**

Contro group1: tibial plateau fracture fixation with
anatomical plate lateral and medial external fixator
antero medial

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Dr Masoud Shayestehazar

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Sari, Mazandaran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University Of Medical Science

Full name of responsible person

Ahmad Ali Enayati

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University Of Medical Science
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

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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