Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 inclusin 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 groupl: 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

Masoud Shayestehazar

Name of organization / entity

Mazandaran University Of Medical Sciences

Country

Iran (Islamic Republic of)

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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 groupl: 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
Street address
Sari, Mazandaran
City
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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
Street address
Sari, Mazandaran

City
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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
Name of organization / entity
Mazandaran Univercity Of Medical Science
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Person responsible for updating data

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Email
Web page address

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