Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing Anterior Minimal Invasive Plate Osteosynthesis (MIPO) with PHILOS plate and Open Reduction Internal Fixation (ORIF) with T-Locking Posterior Plate for Extra-Articular Distal-Third Humeral Fractures: A Randomized Clinical Trial

Protocol summary

Study aim
Comparison of surgical results of extra-articular distal humeral shaft fractures using two methods: minimally invasive plating with a PHILUS plate and open plating with a posterior T-plate

Design
This study was designed as an RCT and examined and compared two surgical methods.

Settings and conduct
Patients with acute and extra-articular distal humerus fractures referred to Shohada Tajrish Hospital will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups using a randomized block design. This study will be conducted in a single-blind manner so that the examining physician, and the data analyst will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: acute extra-articular distal humeral shaft fracture Exclusion criteria: open fractures; having severe underlying diseases that affect the incidence of complications or union, including RA and corticosteroid use, malignancies, etc., nerve or vascular damage before surgery; surgical history of the injured limb; multiple trauma patients; hospitalization in ICU; pathological fracture; or age over 60 or under 20 years.

Intervention groups
Intervention group: Patients underwent MIPO in the supine position and under general anesthesia with a distal and proximal small incision to the fracture site. The plate will be inserted in the opposite direction, from distal to proximal. Control group: Patients underwent ORIF with a posterior T-plate in the lateral position after G. The posterior skin approach and triceps splitting the radial nerve are explored, and the T-plate is inserted posteriorly. All surgeries will be performed by one surgeon and in one center, and no splint will be placed after surgery in both groups.

Main outcome variables
Bleeding, Range of Motion, Surgical incision length, Functional Outcomes, Union time, Complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211201053235N8**
Registration date: **2025-10-10, 1404/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-10, 1404/07/18**
Update count: **0**

Registration date
2025-10-10, 1404/07/18

Registrant information
Name
Meisam Jafari Kafiabadi
Name of organization / entity
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-03-21, 1404/01/01

Expected recruitment end date
2026-09-21, 1405/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing Anterior Minimal Invasive Plate Osteosynthesis (MIPO) with PHILOS plate and Open Reduction Internal Fixation (ORIF) with T-Locking Posterior Plate for Extra-Articular Distal-Third Humeral Fractures: A Randomized Clinical Trial

Public title
Management of Extra-Articular Distal-Third Humeral Fractures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Acute distal humeral shaft fracture consent to participate in the study
Exclusion criteria:
Open fractures having severe underlying diseases that affect the incidence of complications or union, including RA and corticosteroid use,lupus, nerve or vascular damage before surgery previous surgical history of the injured limb multiple fractures or multiple trauma patients hospitalization in the intensive care unit lack of cooperation in follow-up or patient dissatisfaction age over 60 or under 20 heavy smoking
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
We use ten blocks of six to allocate 60 people to two groups of 30. First, we will consider six cards, including 3 cards called group A and 3 cards called group B. As each patient enters, we randomly draw one card from the six cards and, based on the result of the card drawn, the patient is assigned to group A or B. The drawn card is discarded and the next person is assigned to two groups A or B based on the remaining five cards, and this process will continue until the sixth person. The next six people are again selected based on the six randomized cards. This process is repeated for ten blocks of six, and finally we will have two groups of 30 people from two treatments A or B.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding Method in the Study: In this study, an evaluator and observer who is unaware of the type of treatment will be used to measure the outcome variables; therefore, this study will be a single-blind study. The evaluator will be a medical professional who has no knowledge of which method the patient has undergone. Additionally, the forms and data entry checklists will avoid mentioning names to preserve the confidentiality of the type of procedure.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Skin Research Center of Shahid Beheshti University of Medical Sciences
Street address
Skin Research Center, Minou Alley, Shahrdari Street, Shariati Street, Tehran
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Province
Tehran
Postal code
1989934148
Approval date
2025-01-19, 1403/10/30
Ethics committee reference number
IR.SBMU.SRC.REC.1403.051

Health conditions studied

1

Description of health condition studied
Extra-Articular Distal-Third Humeral Fractures
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Bleeding
Timepoint
During surgery
Method of measurement
Through medical records and based on milliliters

2

Description
Range of motion
Timepoint
Patients in the intervention and control groups are visited after surgery five times at intervals of 2, 4, and 12 weeks, and 6 and 12 months post-surgery.
Method of measurement
Using the Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire

3

Description
Surgical incision length
Timepoint
Post-surgery
Method of measurement
Measurement of incision length in centimeters through measurements taken during the operation

4

Description
Functional Outcomes
Timepoint
Patients in the intervention and control groups are visited after surgery five times at intervals of 2, 4, and 12 weeks, and 6 and 12 months post-surgery
Method of measurement
Using the Motor Evaluation Protocol Questionnaire

5

Description
Union time
Timepoint
Patients in the intervention and control groups are visited after surgery five times at intervals of 2, 4, and 12 weeks, and 6 and 12 months post-surgery
Method of measurement
Through radiographic imaging, considering welding, 3 cortices out of four cortices

6

Description
Complications
Timepoint
Patients in the intervention and control groups are visited after surgery five times at intervals of 2, 4, and 12 weeks, and 6 and 12 months post-surgery
Method of measurement
Through examination and radiographic imaging, including cases of infection, intraoperative injuries, implant failure, and the need for reoperation.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients undergoing surgery with minimally invasive plate osteosynthesis (MIPO) using a fibula plate in a supine position under general anesthesia, with two small incisions distal and proximal to the fracture site. The plate will be inserted in a reverse manner from distal to proximal. All surgeries will be performed by a single surgeon at one center, and post-surgery, the patients will not be placed in a splint. Physical therapy will begin after suture removal at two weeks.
Category
Treatment - Surgery

2

Description
Control group: Patients undergoing surgery with open reduction and internal fixation (ORIF) using a T-plate in a lateral position under general anesthesia. In this method, a posterior skin approach is used, and after splitting the triceps, access is gained to the fracture site for reduction. The radial nerve will also be explored, and the T-plate will be placed posteriorly. These surgeries will be performed by a single surgeon at one center, and post-surgery, patients in this group will also not be placed in a splint. Physical therapy will begin after suture removal at two weeks.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-e tajrish hospital
Full name of responsible person
Meisam Jafari Kafiabadi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
5th Floor, Building No. 2, Shahid A'rabi Street, Yaman Street, Chamran Expressway, Tehran, Iran
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
Associate professor
Latest degree
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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
No - There is not 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 is potentially shareable after de-identifying individuals.
When the data will become available and for how long
After the project starts
To whom data/document is available
Everyone in the health system
Under which criteria data/document could be used
Not necessary.
From where data/document is obtainable
Project manager email
What processes are involved for a request to access data/document
Within a week
Comments