

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

Email address

dr.jafari8567@yahoo.com

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, Shahr-dari Street, Shariati Street, Tehran

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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

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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

Meisam Jafari Kafiabadi

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Latest degree

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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