

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of clinical and radiographic outcomes of two fixation methods: percutaneous pinning and external fixator insertion and percutaneous pinning and dorsal bridge plate insertion in distal radius fracture

Protocol summary

Study aim

Determining the clinical and radiographic outcomes of two fixation methods: percutaneous pinning and external fixator insertion and percutaneous pinning and dorsal bridge plate insertion in distal radius fractures.

Design

patients are randomly divided into two groups, the patients in these two groups are matched in terms of age and gender, and one group is placed under external fixator and the other group is placed under dorsal bridge plate. Randomization of individuals is done using simple randomization method based on registration number. The blinding method in this study is single blinded.

Settings and conduct

performing surgery in the operation room of Imam Khomeini, Shariati and Sina hospital

Participants/Inclusion and exclusion criteria

The subjects included in the study were those who had a distal radius fracture and were candidates for surgical treatment with an external fixator or dorsal bridge plate due to articular surface involvement. Inclusion criteria: 1 - Distal radius fracture 2 - Articular surface comminution (type C2 and C3 according to AO classification) 3 - Closed physis Exclusion criteria: 1 - Previous fracture in the same upper limb 2 - Simultaneous fracture in the same upper limb 3 - Evidence of distal radioulnar joint instability (DRUJ) 4 - Neuropathy and vascular involvement of the limb 5 - Uncontrolled rheumatological diseases 6 - Open fracture and wound contamination 7 - Pathological fracture 8 - Active wrist joint infection

Intervention groups

One group of patients underwent pin and external fixator placement, and the other group underwent pin and dorsal bridge plate placement.

Main outcome variables

CRPS symptoms; Tendon complications; Neurological

complications; Wound infection; Quick DASH score; Wrist range of motion (ROM); Grip strength; Radiological parameters including volar tilt; ulnar variance; radial height; radial inclination

General information

Reason for update

Acronym

DRUJ (distal radioulnar joint)

IRCT registration information

IRCT registration number: **IRCT20241112063690N2**

Registration date: **2026-06-09, 1405/03/19**

Registration timing: **retrospective**

Last update: **2026-06-09, 1405/03/19**

Update count: **0**

Registration date

2026-06-09, 1405/03/19

Registrant information

Name

Mohamad Ehsan Shapourgan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7705 9279

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shapoorgan.ehsan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

2023-09-23, 1402/07/01

Actual recruitment end date

2026-02-20, 1404/12/01

Trial completion date

2026-04-07, 1405/01/18

Scientific title

Comparison of clinical and radiographic outcomes of two fixation methods: percutaneous pinning and external fixator insertion and percutaneous pinning and dorsal bridge plate insertion in distal radius fracture

Public title

Comparison of clinical and radiographic outcomes of two fixation methods: percutaneous pinning and external fixator insertion and percutaneous pinning and dorsal bridge plate insertion in distal radius fracture

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

distal radius fracture articular surface comminution (c2-c3 according to AO classification) physical closure

Exclusion criteria:

previous fracture of the same limb ipsilateral fracture of the same limb DRUJ instability neuropathy and vascular disease uncontrolled rheumatologia disease open fracture pathologic fracture active infection of wrist

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **92**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

The researcher and analyst are unaware of the type of surgery performed. The patient and surgeon are aware of the type of surgery performed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences sina hospital

Street address

No. 604, 6th floor, central building of TUMS , Keshavarz blvd

City

tehran

Province

Tehran

Postal code

1461884513

Approval date

2024-10-07, 1403/07/16

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1403.088

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

distal radius fracture

ICD-10 code

S52.5

ICD-10 code description

Fracture of lower end of radius

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

Device removal time; , incidence of CTS, incidence of CRPS, tendon injury, infection, incidence of device failure, radiological parameters volar tilt, ulnar variance, radial height, radial inclination

Timepoint

after performing surgery and before device removal

Method of measurement

physical examination and radiography

2**Description**

grip strength, range of wrist motion, quick dash score

Timepoint

after device removal

Method of measurement

physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: distal radius fracture that underwent external fixator insertion, It is a well-known surgical treatment for distal radius articular surface fractures. Two distal and two proximal pin screws are placed at the fracture site and connected to each other with the help of two rods.

Category

Treatment - Surgery

2

Description

Intervention group: distal radius fracture that underwent dorsal bridge plate insertion, A method introduced for comminuted fractures of the distal radius that uses a long plate posterior to the fracture site, which bridges the fracture site and is fixed on both sides with screws.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Mohamad's Ehsan Shapourgan

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Recruitment center

Name of recruitment center

Sina hospital

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohamad Ehsan Shapourgan
Position
Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available