Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Email address

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 reumatologia 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
Street address
Shariati hospital, Jalal al Ahmad St, Tehran
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1411713135
Phone
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shapoorgan.ehsan@gmail.com

2

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Mohamad's Ehsan Shapourgan
Street address
Imam Khomeini St. Hasan abad sq.
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3

Recruitment center
Name of recruitment center
Imam Khomeini hospital complex
Full name of responsible person
Mohamad Ehsan Shapourgan
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Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Central University Organization, Qods Street, Keshavarz Boulevard, Tehran
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Postal code
141765383761
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
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

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Latest degree

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Phone

+98 21 8490 1000

Email

rz_kamrani@yahoo.com

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