# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of the therapeutic outcomes of intra-articular distal radius fractures treated with locking plate alone versus locking plate combined with external fixator.

## Protocol summary

**Study aim**
Comparison of the therapeutic outcomes of intra-articular distal radius fractures treated with locking plate alone versus locking plate combined with external fixator.

**Design**
The present study is an open-label, parallel-group randomized clinical trial (using block randomization) conducted on 64 patients.

**Settings and conduct**
In this open-label randomized clinical trial, patients who are candidates for distal radius surgery at Vali-Asr Hospital in Arak will be randomly assigned to two groups (A and B) using block randomization. Blinding will not be performed due to the nature of the study, and the study outcomes will ultimately be compared between the two groups.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients aged 18–60 years with intra-articular distal radius fractures; surgical intervention performed within a maximum of 10 days after injury; and provision of written informed consent to participate in the study and attend follow-up visits at 2 weeks and at 1, 2, and 6 months. Exclusion criteria: Open fractures or contamination of the surgical site; Presence of uncontrolled diabetes, renal failure, or long-term corticosteroid use.

**Intervention groups**
Group I (Volar Locking Plate, VLP): Patients undergo open reduction and internal fixation (ORIF) via the volar Henry approach. After anatomical reduction of fracture fragments, a volar locking plate is applied to the distal radius and fixation is confirmed with fluoroscopy. Group II (VLP + External Fixator): After ORIF with a volar locking plate as described above, a dynamic bridging external fixator is additionally applied based on the principle of ligamentotaxis to enhance stability and maintain reduction.

**Main outcome variables**
Range of motion of the wrist joint, pain score, Disabilities of the Arm, Shoulder and Hand (DASH) score, Mayo Wrist Score, and time to return to work.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20191104045328N55**
Registration date: **2026-05-12, 1405/02/22**
Registration timing: **prospective**

Last update: **2026-05-12, 1405/02/22**
Update count: **0**

**Registration date**
2026-05-12, 1405/02/22

**Registrant information**

**Name**
Amin Haji seyyed hoseini

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-05-20, 1405/02/30

**Expected recruitment end date**
2026-08-21, 1405/05/30

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the therapeutic outcomes of intra-articular distal radius fractures treated with locking plate alone versus locking plate combined with external fixator.

**Public title**
Comparison of Two Surgical Methods for Intra-Articular Distal Radius Fractures
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients aged 18–60 years with intra-articular distal radius fractures (AO classification types C2 and C3), based on radiographic imaging. Surgery performed within a maximum of 10 days after injury. Written informed consent from the patient for participation and follow-up at 2 weeks, and 1, 2, and 6 months.
**Exclusion criteria:**
Open fracture or contamination of the surgical site. Presence of a systemic disease affecting bone healing (such as uncontrolled diabetes, renal failure, or long-term corticosteroid use).
**Age**
From **18 years** old to **60 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **64**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Participants will be assigned to the two intervention groups in the order of enrollment and according to a pre-generated randomization sequence. This sequence will be unpredictable, and its arrangement will be completely random. Block randomization with blocks of four will be used for sample allocation. Accordingly, using random number generation software with a block randomization method, a randomization sequence appropriate to the required sample size for the three groups will be generated. Initially, all possible arrangements of the two labels, A and B, within blocks of four will be created. Then, one block will be randomly selected with replacement from among all blocks, and the arrangement pattern within that block will be used for participant allocation. The selected block will then be returned to the main pool, and another block will be randomly selected again. All these procedures will be performed using software called Sealed Envelope. Using this method, allocation concealment will also be maintained. Allocation concealment refers to preventing prediction of participants' assignment to groups. In fact, the researcher will not be able to predict which group the next participant will be assigned to.
**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 Arak University of Medical Sciences
**Street address**
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran.
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**Approval date**
2026-04-12, 1405/01/23
**Ethics committee reference number**
IR.ARAKMU.REC.1405.028

## 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**
Range of motion of the wrist joint
**Timepoint**
2 weeks, 1, 2, and 6 months post-surgery
**Method of measurement**
Goniometer

**2**

**Description**
Pain score
**Timepoint**
2 weeks, 1, 2, and 6 months post-surgery
**Method of measurement**
Visual Analog Scale

**3**

**Description**
Disabilities of the Arm, Shoulder and Hand Score (DASH)
**Timepoint**
2 weeks, 1, 2, and 6 months post-surgery
**Method of measurement**
The standardized Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire

**4**

**Description**
Mayo Wrist Score
**Timepoint**
2 weeks, 1, 2, and 6 months post-surgery
**Method of measurement**
Mayo Wrist Score

**5**

**Description**
Time to return to work
**Timepoint**
Within 6 months after surgery
**Method of measurement**
Medical history

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Group I – Volar Locking Plate (VLP): In this group, patients are treated using Open Reduction and Internal Fixation (ORIF) via the anterior volar (Henry) approach. Following regional or general anesthesia, a skin incision is made along the Flexor Carpi Radialis (FCR) tendon. Initially, the fracture fragments are reduced to their anatomical position through direct manipulation and, if necessary, with the use of pins. The interval between the radial artery and the FCR tendon is then dissected, and the tendon is retracted ulnarly. The Pronator Quadratus (PQ) muscle is detached from the volar surface of the radius, providing full visualization of the sigmoid notch to assess the fracture site and the position of the plate. Subsequently, the VLP is placed on the volar surface of the radius, and locking screws are inserted to ensure axial stability and prevent secondary displacement. Fluoroscopic control in anteroposterior (AP) and lateral views is performed to confirm precise reduction and proper plate positioning. Finally, the wound is closed in layers, a sterile dressing is applied, and the limb is immobilized with a short arm splint for a short period to allow for early passive motion.
**Category**
Treatment - Surgery

**2**

**Description**
Group II – Volar Locking Plate with External Fixator:In this group, all of the aforementioned steps for internal fixation are first performed, and the plate is fixed in place using the Volar Locking Plate technique. Subsequently, to enhance stability and maintain longitudinal forces, a dynamic external fixator is applied based on the principle of ligamentotaxis.For this purpose, in bridging external fixation of the distal radius, a longitudinal incision is initially made over the radial aspect of the distal radial diaphysis. Through blunt dissection down to the bone, the superficial radial nerve and the lateral antebrachial cutaneous branch are carefully protected. Thereafter, two bicortical pins are inserted into the middle–lateral aspect of the radius, proximal to the fracture site.Next, a small incision is created over the second metacarpal between the first dorsal interosseous muscle and the extensor tendons of the index finger. Two pins are then inserted from the second metacarpal toward the third metacarpal, engaging one cortex of the latter, in order to create a three-point fixation construct. After connecting the pins using clamps and bars, the external fixation frame is assembled.Finally, the fracture is reduced, and the adequacy of reduction is confirmed under fluoroscopic guidance. The connections are then tightened, and complete stability with maintenance of reduction is verified. The fixator remains in place for one month and is removed upon observation of early signs of bony callus formation.
**Category**
Treatment - Surgery

## Recruitment centers

**1**

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## Sponsors / Funding sources

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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**
Arak 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**
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## Person responsible for updating data

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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**
Yes - There is 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**
No - There is not 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**
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.
**When the data will become available and for how long**
Access will commence from August 21, 2026, until August 21, 2029, for a duration of 3 years.
**To whom data/document is available**
University researchers
**Under which criteria data/document could be used**
Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.
**From where data/document is obtainable**
University researchers and university professors can request Dr. Ahmadreza Behrouzi to use the data after contacting the relevant professor via message or email. Dr. Hesamuddin Modiri: Phone: 09183615107 Email: modir.he@gmail.com, Address: Valiasr Hospital, Arak, Vice-Chancellor of Hospital Education
**What processes are involved for a request to access data/document**
Letter writing should be done with professors and universities.
**Comments**