Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Effect of Intra-Articular Hyaluronic Acid Injection on Postoperative Stiffness in Patients with Distal Radius Fractures Treated with Volar Plate Fixation (ORIF): A Randomized Clinical Trial

Protocol summary

Study aim

To determine the effect of a single intra-articular injection of Hyaluronic Acid on wrist range of motion at 12 weeks postoperatively in patients undergoing volar plate fixation for distal radius fracture

Design

This study is a randomized, controlled, parallel-group clinical trial with a two-arm design and blinded outcome assessment. It is conducted as a phase II trial including 60 patients. Randomization is performed using block randomization with a 1:1 allocation ratio

Settings and conduct

This is a randomized, parallel, double-blind clinical trial conducted at Imam Khomeini Hospital, Tehran. Adult patients (18–70 years) undergoing ORIF for distal radius fractures are allocated into two groups using block randomization with sealed opaque envelopes. The intervention group receives a single 2-mL intra-articular hyaluronic acid injection at the end of surgery; the control group receives no injection. Both patients and outcome assessors are blinded. Outcomes (ROM, pain, and function) are assessed at weeks 2, 6, and 12

Participants/Inclusion and exclusion criteria

Inclusion: Adult patients with acute, closed distal radius fractures requiring volar plate fixation Exclusion: Conditions that may interfere with the intervention, safety, or study follow-up

Intervention groups

Intervention Group (HA): Patients receive a single 2-mL intra-articular injection of hyaluronic acid (20 mg sodium hyaluronate in 2 mL) after completion of surgery and wound closure. Control Group: Patients do not receive any intra-articular injection and are managed with standard postoperative care following ORIF.

Main outcome variables

Primary outcome: Wrist range of motion (ROM) at week 12. Secondary outcomes: Pain (VAS) at weeks 2, 6, 12; wrist function (Quick-DASH) at weeks 6, 12; postoperative complications (stiffness, swelling, infection) up to week 12.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251202068189N1**
Registration date: **2026-01-28, 1404/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-28, 1404/11/08**
Update count: **0**

Registration date

2026-01-28, 1404/11/08

Registrant information

Name
ibrahim alkhuzaie
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 915 621 0690
Email address
e-khazaee@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Intra-Articular Hyaluronic Acid Injection on Postoperative Stiffness in Patients with Distal Radius Fractures Treated with Volar Plate Fixation (ORIF): A Randomized Clinical Trial

Public title
Effect of Hyaluronic Acid on stiffness of wrist
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Adults aged 18 to 70 years Acute, closed distal radius fracture requiring ORIF with volar plate Ability and willingness to provide written informed consent and adhere to the follow-up schedule
Exclusion criteria:
Open or pathological fractures Previous surgery or trauma to the affected wrist Systemic inflammatory joint disease (e.g., rheumatoid arthritis) Known allergy to Hyaluronic Acid or its components Local or systemic infection Inability to participate in rehabilitation or follow-up Intraarticular fracture
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients, after providing informed consent, are randomly assigned to the intervention or control groups using block randomization with a 1:1 allocation ratio. The unit of randomization is the individual patient, and no stratified randomization is applied. The random sequence is generated using statistical software based on blocks of variable size to minimize predictability of group assignment. Allocation concealment is ensured by using sequentially numbered, opaque, sealed envelopes containing the group allocation codes, which are opened only after completion of surgery and wound closure, thereby minimizing selection bias.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants (patients) are blinded to their group allocation. Outcome assessors, including physiotherapists and personnel responsible for measuring range of motion, pain scores, and functional outcomes, are blinded to group assignment. The statistical analyst performs data analysis using anonymized group codes and is not aware of the treatment allocation. Due to the nature of the intervention, the operating surgeon is aware of the group assignment at the time of intervention; however, the surgeon has no role in outcome assessment, data collection, or statistical analysis. All participants are fully informed about their participation in the study, and written informed consent is obtained; lack of patient awareness of study participation is not involved.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Imam Khomeini Hospital Complex – Tehran University of Medical Sciences
Street address
Imam Khomeini Hospital Complex, Keshavarz Boulevard, Chamran Highway, Tehran, Iran
City
tehran
Province
Tehran
Postal code
1461884513
Approval date
2025-09-30, 1404/07/08
Ethics committee reference number
IR.TUMS.IKHC.REC.1404.293

Health conditions studied

1

Description of health condition studied
Postoperative joint stiffness, distal radius fracture, limitation of wrist range of motion
ICD-10 code
M25.63
ICD-10 code description
Stiffness of wrist, not elsewhere classified

Primary outcomes

1

Description
Wrist range of motion (flexion–extension), measured using a goniometer by a blinded assessor at 12 weeks

post-operation.

Timepoint

Wrist flexion–extension ROM will be measured at week 6 and at week 12 after surgery

Method of measurement

Wrist joint range of motion will be measured using a standard goniometer by a trained and blinded assessor.

Secondary outcomes

1

Description

Pain intensity measured using the Visual Analogue Scale by a blinded assessor at weeks two, six, and twelve after surgery.

Timepoint

Pain intensity measured at weeks two, six, and twelve after surgery.

Method of measurement

Visual Analogue Scale by a blinded assessor

2

Description

Wrist functional status measured using the Quick Disabilities of the Arm, Shoulder and Hand questionnaire at weeks six and twelve after surgery.

Timepoint

at weeks six and twelve after surgery

Method of measurement

the Quick Disabilities of the Arm, Shoulder and Hand questionnaire at weeks six and twelve after surgery.

3

Description

Postoperative complications including persistent joint stiffness, joint swelling, and infection assessed up to week twelve after surgery.

Timepoint

up to week twelve after surgery

Method of measurement

Postoperative complications including persistent joint stiffness, joint swelling, and infection will be assessed through clinical examination by the treating physician and documented using a standard clinical evaluation checklist.

Intervention groups

1

Description

Intervention group: Intervention Group (HA group): Patients will receive a single 2 mL intra-articular injection of hyaluronic acid (e.g., sodium hyaluronate 20 mg/2 mL) after wound closure.

Category

Other

2

Description

Control Group: Patients will receive no injection and standard postoperative care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital complex

Full name of responsible person

Aidin Arabzadeh

Street address

Imam Khomeini Hospital Complex, Keshavarz Boulevard, Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 915 621 0690

Email

e-khazaee@student.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

Enghelab Ave

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 912 454 8064

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

Ibrahim Alkhuzaie

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Orthopedics

Street address

No.239, between Gisha St. 36 and 38

City

Tehran

Province

Tehran

Postal code

1448933137

Phone

+98 915 621 0690

Email

khazaei70@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Omid Salkhori

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Imam Khomeini Hospital Complex, Keshavarz Boulevard, Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 922 483 8234

Email

omidsalkhorii303@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ibrahim Alkhuzaie

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Orthopedics

Street address

Imam Khomeini Hospital Complex, Keshavarz Boulevard, Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1448933137

Phone

+98 915 621 0690

Fax

Email

e-khazaee@student.tums.ac.ir

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

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

Title of shared documents: De-identified raw dataset of primary and secondary outcome measures. Details: Individual participant data will be shared only after complete removal of all identifiable information (including names, national identification numbers, and hospital record numbers). The shared dataset will include wrist range-of-motion measurements, pain scores, functional questionnaire results, and postoperative complication records. Data will be provided exclusively in a fully de-identified format and only for research purposes, upon formal request and approval by the ethics committee

When the data will become available and for how long

Access to the shared dataset will begin six months after publication of the final study results and will remain available for at least three years thereafter

To whom data/document is available

Requests for access to the study data may be submitted only by researchers and academic investigators affiliated with recognized universities or research institutions. Applicants must present a clearly defined scientific purpose and obtain ethics committee approval. Data will not be shared with individuals or organizations seeking access for commercial or industrial purposes

Under which criteria data/document could be used

Access to de-identified data will be granted only if the applicant provides a defined research proposal, clear scientific objectives, and an appropriate analysis plan. Use of the data is restricted to academic and statistical research purposes only. Commercial use, promotional use, or redistribution of the dataset is strictly prohibited. Applicants must sign a confidentiality agreement and are permitted to use the dataset solely within the scope of the ethics-approved research protocol. Further sharing of the dataset with third parties without written permission is not allowed

From where data/document is obtainable

Applicants who wish to obtain the study data or related documentation may submit their official request primarily via email, followed by telephone contact if needed. The designated contact person for responding to data requests is Dr. Ebrahim Khazaee. Email addresses for correspondence: E-khazaee@student.tums.ac.ir khazaei70@yahoo.com Telephone number: +989156210690 If in-person or postal correspondence becomes necessary, arrangements will be made through the above email addresses and the postal address will be provided accordingly. Applicants must submit a clear research objective and a relevant study proposal along with their request

What processes are involved for a request to access data/document

The process for obtaining the requested dataset consists of several steps. Applicants must first submit an official request via email, including their research objective and study proposal. The request will be reviewed within 7–14 business days, and additional clarification may be requested if needed. Following initial approval, the request will be evaluated for ethical compliance, which typically requires 14–30 business days. After final approval, the de-identified dataset will be provided within 14 business days through a secure email or restricted access link. Overall, the estimated time required to receive the dataset ranges from 4 to 8 weeks, depending on administrative processing time and applicant responsiveness

Comments