Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparison between bolus and daily vitamin D3 supplementation in distal radius fracture

Protocol summary

Study aim

1. Comparing union rate of distal radius fractures between the group receiving bolus vitamin D3 and the group receiving vitamin D3 2. Comparing complications such as non-union, union with deformity or infection between the two groups

Design

Randomized, parallel-group, unblinded, phase 1-2 clinical trial on 96 patients who, after entering the study, will be assigned to two groups in a permutation random block of 6.

Settings and conduct

In this study, patients with isolated distal radius fractures aged over fifty years and have undergone pcp with the less than 20 ng/dl of vitamin d3 is will be randomly assigned to two groups of 48 people. One group will be prescribed oral vitamin D3 tablets for six weeks, and the other group will be prescribed a 300,000 unit vitamin D3 ampoule, and both groups will be given daily calcium supplements. The results of the union in the two groups will be monitored for 12 weeks.

Participants/Inclusion and exclusion criteria

Patients diagnosed with Fernandez type 1 distal radius fracture who are over 50 years old and have undergone closed reduction and pcp. Patient with other simultaneous fractures or with an old fracture in the same location or with any metabolic, neoplastic, or rheumatologic disease, or with any cytotoxic ,hormonal or supplemental drug history will be excluded from the study.

Intervention groups

Both groups undergo closed pin fixation. In one group, vitamin D3 supplementation is given daily in tablets and in the other group, in bolus form in ampoules. Both groups are given equal amounts of oral calcium in tablets.

Main outcome variables

The intended outcome is the time to complete fracture union (based on radiological and clinical criteria), which includes the following: Radiological: Formation of bone callus on all 4 sides of the fracture Clinical: No pain with direct pressure + no movement at the fracture site by week 12 after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260629070011N1**
Registration date: **2026-07-24, 1405/05/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-24, 1405/05/02**
Update count: **0**

Registration date

2026-07-24, 1405/05/02

Registrant information

Name
Arash Rashidi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 918 873 8198
Email address
arashrashidi20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison between bolus and daily vitamin D3 supplementation in distal radius fracture

Public title
The comparison between bolus and daily vitamin D3 supplementation in distal radius fracture
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with distal radius fracture aged at least 50 years patients with type 1 Fenrandez classification managed by pcp
Exclusion criteria:
patients with simultaneous fractures in other bones of body are rolled out from the study patients with old fracture in the same place are rolled out from the study patients with chronic metabolic or neoplastic or rheumatologic diseases are rolled out from the study patients with history of cytotoxic or hormonal or supplementation drug consumption are rolled out of the study
Age
From **50 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial, participants will be randomly assigned to two groups after entering the study in a permutation block of 6. The first group will receive injectable vitamin D3 and the second group will receive oral vitamin D3. After obtaining informed consent and confirming the inclusion criteria, the patient's basic information will be recorded and the patient will be placed in the relevant stratum. Group assignment will be based on a pre-generated sequence. All steps will be performed by a research assistant who is not involved in the intervention. This method ensures that the assignment of patients to groups is completely random and free from bias.
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
ethic committee of Arak University of Medical sciences
Street address
Armaghan Ally, Nabovat Avenue , Urmia city
City
Urmia
Province
West Azarbaijan
Postal code
5719915883
Approval date
2026-06-14, 1405/03/24
Ethics committee reference number
IR.ARAKMU.REC.1405.137

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
The time of complete fracture union (based on radiological and clinical criteria)
Timepoint
4th and 12th weeks after fixation
Method of measurement
Radiological: Formation of bone callus on 4 sides of the fracture and Clinical: No pain with direct pressure + no movement at the fracture site until 12 weeks after treatment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Approximately half of the patients in the study (about 48 patients) will undergo closed

reduction and percutaneous pin fixation for their fracture. They will then receive vitamin D3 as a bolus via intramuscular injection. Patients will also receive oral calcium supplements in tablet form. All medications are manufactured in Iran and no specific brand will be imposed on the patients. The patients will then be followed up for 12 weeks, and the results regarding fracture union will be compared with the control group.

Category

Treatment - Drugs

2

Description

Control Group: Approximately half of the patients in the study (about 48 patients) will undergo closed reduction and percutaneous pin fixation for their fracture. They will then receive vitamin D3 orally as a daily tablet. Patients will also receive oral calcium supplements in tablet form. All medications are manufactured in Iran and no specific brand will be imposed on the patients. The patients will then be followed up for 12 weeks, and the results regarding fracture union will be compared with the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Arak Valiasr Hospital
Full name of responsible person
Arash Rashidi
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Armaghan Ally, NAbovat Avenue, Urmia City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Behzad Khansari Nezhad
Street address
Armaghan Ally,Nabovat Avenue, Urmia city
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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

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Arash Rashidi
Position
Resident of Orthopedics
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Arash Rashidi
Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable