

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of vitamin C and Vitamin D effect on distal radius fractures treated with external fixation+PCP

Protocol summary

2022-06-20, 1401/03/30

Study aim

Evaluation of the results of using vitamins D and C in the prevention of CRPS

Design

Phase 2 clinical trial in patients with acute distal radius fractures requiring fixation surgery that the control group does not have.

Settings and conduct

After the necessary evaluations, if the inclusion criteria are met, the patients are transferred to the operating room, closed, reduced and pinned, and then an external fixator is installed for them.

Participants/Inclusion and exclusion criteria

Distal radius fracture; ability to receive oral vitamins C and D; indication for fixation of distal radius fracture by external fixator and pin method; osteoporosis; patients with other fractures, ligament damage or neuropathy; previous fracture involved in the radius

Intervention groups

Patients aged 18 to 60 years with acute distal radius fracture require fixation surgery with external fixator and pin

Main outcome variables

Pain in the range of motion; amount of patient activity and surgical complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211201053235N6**

Registration date: **2022-06-20, 1401/03/30**

Registration timing: **prospective**

Last update: **2022-06-20, 1401/03/30**

Update count: **0**

Registration date

Registrant information

Name

Meisam Jafari Kafiabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

Email address

dr.jafari8567@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of vitamin C and Vitamin D effect on distal radius fractures treated with external fixation+PCP

Public title

Treatment of distal radius fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Distal radius fracture Ability to receive oral vitamins C and D Indication for fixation of distal radius fracture by external fixator and pin method

Exclusion criteria:

Osteoporosis Patients with other fractures, ligament damage or neuropathy Previous fracture involved in the radius

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Yemen Street, Shahid Chamran Highway, Iran, Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2022-04-24, 1401/02/04

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.038

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

Fracture at wrist and hand level

ICD-10 code

S62

ICD-10 code description

Fracture at wrist and hand level

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

Pain

Timepoint

2 weeks, 6 weeks, 12 weeks and 6 and 12 months after surgery

Method of measurement

Visual analogue scale

Secondary outcomes**1****Description**

Range of motion

Timepoint

6 weeks, 12 weeks and 6 and 12 months after surgery

Method of measurement

Patient examination

Intervention groups**1****Description**

Intervention group: Patients with distal radius fractures who were treated with pins and external fixators and found vitamins C and D after surgery

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada Tajrish Hospital

Full name of responsible person

Dr. Meisam Jafari Kafiabadi

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Tajrish square

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Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Meisam Jafari Kafiabadi

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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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
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
After finishing patient recruitment
When the data will become available and for how long

After finishing patient recruitment
To whom data/document is available
After finishing patient recruitment
Under which criteria data/document could be used
After finishing patient recruitment
From where data/document is obtainable
After finishing patient recruitment
What processes are involved for a request to access data/document
After finishing patient recruitment
Comments