Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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
2022-06-20, 1401/03/30

Registrant information
Name
Meisam Jafari Kafiabadi
Name of organization / entity
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Iran (Islamic Republic of)
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+98 21 2271 8000
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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
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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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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

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