

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Triple blind evaluation of the efficacy of oral calcium Hydroxy-apatite on post-operative pain, grip and bone mineral density after distal radius fracture surgery

Protocol summary

Study aim

Comparison of the effectiveness of oral calcium hydroxyapatite with calcium carbonate in patients after distal radius fracture fixation surgery

Design

A randomized, triple-blinded, phase 3 clinical trial with a parallel-group design of 150 patients

Settings and conduct

All patients over 45 years of age referred to the trauma emergency department of Shariati Hospital with distal radius fractures who are candidates for surgery will be included in the study. Medication packages with the same appearance which randomly contain one of two calcium supplements will be assigned to patients admitted to the study. Thereby, the patient and the physician, and the data analyzer will not be informed of the drugs allocated.

Participants/Inclusion and exclusion criteria

All patients over 45 years of age referred to the trauma emergency department of Shariati Hospital with distal radius fractures who are candidates for surgery will be included in the study from April 2022 to April 2023. Patients who are not candidates for surgery due to medical problems with an ASA score of 3 or higher will be excluded from the study. Patients who have received osteoporosis treatments before surgery, including bisphosphonates, calcium and vitamin D supplements, or hormone therapy, will be excluded from the study. Patients with mental disorders who may not be able to cooperate in study will be excluded.

Intervention groups

Patients are randomly divided into case and control groups after surgery. The control group will receive daily calcium carbonate, vitamin D and Alendronate in addition to the post-up protocol while the case group will receive oral calcium hydroxyapatite, vitamin D and Alendronate in addition to the post-up protocol.

Main outcome variables

-Bone density -Pain - Union of fracture -Grip force -
Recurrence of fracture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210712051854N2**

Registration date: **2022-04-16, 1401/01/27**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-16, 1401/01/27**

Update count: **0**

Registration date

2022-04-16, 1401/01/27

Registrant information

Name

Mohammad Hossein Nabian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 1444

Email address

dr.nabian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Triple blind evaluation of the efficacy of oral calcium Hydroxy-apatite on post-operative pain, grip and bone mineral density after distal radius fracture surgery

Public title

Comparison of the effect of oral calcium Hydroxy-Apatite and calcium carbonate on prognosis of distal radius fracture surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over 45 years of age with distal radius fracture referring to Shariati Hospital

Exclusion criteria:

Patients received treatment of osteoporosis including Bisphosphonate, calcium, vitamin D and Hormone therapy prior to the surgery Patients not being candidate for surgery due to specific medical condition with ASA score=3 or above Patients with mental disorders who may not adhere to the study

AgeFrom **45 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **150****Randomization (investigator's opinion)**

Randomized

Randomization description

150 drug packs containing vitamin D supplements, alendronate, and one of the two types of calcium carbonate or calcium hydroxyapatite supplements are prepared by the project sponsoring company with the same appearance and delivered to the researchers. The allocation of one of the two types of calcium supplements will be done in such a way that each type of supplement is present in 75 packages out of a total of 150 packages. Randomization will be done by randomizer.org software. Numbers from 1 to 150 will be arranged randomly. Based on the generated random sequence, each patient will be assigned a number in order of referral. (The first random sequence number to the first Patient, the second random sequence number to the second patient ...) Numbers 1 to 75 will be in the calcium hydroxyapatite group and numbers 76 to 150

will be in the calcium carbonate group. Thereby, the patient and the physician, and the data analyzer will not be informed of the drugs allocated. For confidence, there will be two additional copies of the decoded table of numbers and contents of the packages in the hand of researchers and data analyzers, which will not be opened until the end of the research.

Blinding (investigator's opinion)

Triple blinded

Blinding description

150 packages of drugs containing tested drugs with the same appearance are prepared by the sponsoring company. Using simple randomization by computer software, one of the two types of calcium supplements is placed in each packet, and an ID is assigned to each packet. The coding table of IDs and its contents is prepared in a sealed envelope that will not be opened until the end of the study. In this way, the therapist and the patient and the data analyst will not be aware of the contents of the packages and the study will be conducted in a triple-blind manner.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of School of Medicine-
Tehran University of Medical Sciences

Street address

Building no.1, Northern gate of the university,
Poursina St. Qods St. Enqelab St.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-02-27, 1400/12/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1426

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

distal radius fracture

ICD-10 code

S52.5

ICD-10 code description

Primary outcomes

1

Description

bone mineral density

Timepoint

Immediately after surgery, 3 months after surgery, 6 months after surgery

Method of measurement

dual-energy x-ray absorptiometry scan

2

Description

pain rate

Timepoint

Immediately after surgery, 3 months after surgery, 6 months after surgery

Method of measurement

Visual Analog Scale Questionnaire

3

Description

union of fracture

Timepoint

monthly

Method of measurement

Radiography

Secondary outcomes

1

Description

Grip Force

Timepoint

After surgery, 3 months after surgery, 6 months after surgery

Method of measurement

Measuring with Grip force meter

2

Description

Possible side effects of the drug

Timepoint

3 months after surgery- 6 months after surgery

Method of measurement

Patient's Record and History

3

Description

Possible surgical complications

Timepoint

3 months after surgery- 6 months after surgery

Method of measurement

Patient's Record and History

Intervention groups

1

Description

intervention group: In addition to follow up protocol (referring to clinic 1,3,6,12 weeks after surgery) and exercises to maintain range of motion of hand joints ,receives oral Calcium Hydroxy apatite supplement daily for 1 month(n=30),Alendronate 70 mg weekly for 3 month(n=12) and pearl of vit D3 50000 every two week (n=6).

Category

Treatment - Drugs

2

Description

Control group:In addition to follow up protocol (referring to clinic 1,3,6,12 week after surgery) and exercises to maintain the range of motion of hand joints,receives oral Calcium Carbonate supplement daily for 1 month(n=30),Alendronate 70 mg weekly for 3 month(n=12) and pearl of vit D3 50000 every two week (n=6).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr. Mohammad Hossein Nabian

Street address

Jalal-e-Al-e-Ahmad Hwy

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Daroo Salamat Pharmed

Full name of responsible person

Dr. Negar Mosavi Hasab

Street address

Unit 4, No. 27, Sharifi Brothers Alley, Above of Vanak Square, Valiasr St.

City
Tehran

Province
Tehran

Postal code
1969813635

Phone
+98 21 8819 2740

Email
info@darooosf.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Daroo Salamat Pharmed

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Daroo Salamat Pharmed

Full name of responsible person
Dr. Negar Mosavi Hasab

Position
Technical Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
Unit 4, No. 27, Sharifi Brothers Alley, Above of Vanak Square, Valiasr St.

City
Tehran

Province
Tehran

Postal code
1969813635

Phone
+98 21 8819 2741

Email
Negar.moosavi@darooosf.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammad Hossein Nabian

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 1000

Email
mh-nabian@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mobina Gharib

Position
Medical Student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 1000

Email
mobina.gharib@yahoo.com

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

make this available

Data Dictionary

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

Title and more details about the data/document

All data is potentially shareable after anonymizing identifications.

When the data will become available and for how long

After printing the results as an article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For further research purposes and analysis

From where data/document is obtainable

In order to receive the data, it is necessary to refer to the scientific accountant or the corresponding author of the article

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

An official letter or e-mail

Comments