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
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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
Age
From **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 size
Target 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

Fracture of lower end of radius

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 surgey
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 ,recieves 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,recieves 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
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1969813635
Phone
+98 21 8819 2740
Email
info@daroosf.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.
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Assistant Professor
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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
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General Practitioner
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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