

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Triple blind evaluation of the efficacy of oral calcium Hydroxy-apatite on postoperative pain and bone mineral density in patients after pertrochanteric fracture surgery

Protocol summary

Study aim

Comparison of the effectiveness of oral calcium hydroxyapatite with calcium carbonate in patients after pertrochanteric 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 65 years referred to the trauma emergency department of Shariati Hospital with hypertrophic fractures who are candidates for surgery will be included in the study. The method of group selection is done in a triple-blind way so that neither the patient nor the physician nor the statistical analyzer has any knowledge of the patient group (case/control).

Participants/Inclusion and exclusion criteria

All patients over 65 years referred to the trauma emergency department of Shariati Hospital with pertrochanteric fractures who are candidates for surgery and have the necessary mental health to cooperate in the research, 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, are excluded from the study.

Intervention groups

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

Main outcome variables

Pain rate; Bone density; Recurrence of fracture; Union situation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210712051854N1**

Registration date: **2022-03-14, 1400/12/23**

Registration timing: **prospective**

Last update: **2022-03-14, 1400/12/23**

Update count: **0**

Registration date

2022-03-14, 1400/12/23

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 postoperative pain and bone mineral density in patients after pertrochanteric fracture surgery

Public title
Comparison of the effect of calcium carbonate and calcium hydroxyapatite supplementation on the prognosis of pertrochanteric fracture surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients over 65 years referred to Trauma Emergency of Shariati Hospital with pertrochanteric fracture who are candidates for surgery
Exclusion criteria:
Patients who are not candidates for surgery due to medical problems with an ASA score of 3 or higher
Patients receiving osteoporosis treatments including bisphosphonates, calcium and vitamin D supplements, or hormone therapy prior to surgery

Age
From **65 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 packages of drugs containing tested drugs is 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.

Blinding (investigator's opinion)
Triple blinded

Blinding 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 by random numbers table and in such a way that each type of supplement is present in 75 packages out of a total of 150 packages. Researchers will assign medication packages to patients admitted to the study, respectively. 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.

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.1400.1427

Health conditions studied

1

Description of health condition studied

Pertrochanteric Fracture

ICD-10 code

S72.1

ICD-10 code description

Pertrochanteric fracture

Primary outcomes

1

Description

Pain Rate Score

Timepoint

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

Method of measurement

Visual Analog Scale Questionnaire

2

Description

Bone Mineral Density

Timepoint

Immediately after surgery, 6 months after surgery

Method of measurement

Bone-marrow densitometry

3

Description

Fracture Union

Timepoint

Every month

Method of measurement

Radiography

Secondary outcomes

1

Description

Possible side effects of the drug

Timepoint

3 months after surgery, 6 months after surgery

Method of measurement

Patient's Record and History

2

Description

Quadriceps Muscle Strength

Timepoint

After surgery, Third months follow-up, Sixth month follow-up

Method of measurement

Motor Function Measure

3

Description

Weight Bearing Time

Timepoint

3 months after surgery, 6 months after surgery

Method of measurement

Patient's Record and History

Intervention groups

1

Description

Control group: In addition to the post-protocol, daily calcium carbonate supplement for one month (totally, 30 tablets), Alendronate 70 mg once a week for three

months (totally, 12 tablets), 3-Pearl Vit D 50000, one every two weeks for three months (totally, six tablets). All medicines and supplements are manufactured by Daru Salamat Pharmed Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Intervention group: In addition to the post-protocol, daily calcium hydroxyapatite supplement for one month (totally, 30 tablets), Alendronate 70 mg once a week for three months (totally, 12 tablets), 3-Pearl Vit D 50000, one every two weeks for three months (totally, six tablets). All medicines and supplements are manufactured by Daru Salamat Pharmed Pharmaceutical Company.

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.

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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

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sepehr Metanat

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

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