Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of anti-osteoporosis therapies on the repair of osteoporotic fractures in patientss admitted to the orthopedic ward

Protocol summary

Study aim

Determination of the effect of anti-osteoporosis drugs on osteoporotic fractures repair in hospitalized patients

Design

In this research, 75 eligible patients referring to Imam Khomeini Hospital of sari suffering from osteoporotic fracture were chosen purposefully and were randomly divided into three groups of control and intervention one and two by Table of random numbers.

Settings and conduct

This study was conducted at Imam Khomeini Hospital and among patients who entered the study according to inclusion criteria. Then, patients will be divided into three groups according to the random numbers table. The first group, after the surgery, received 1200 mg daily calcium, vitamin D 800 units and alendoronitis ; 70 mg / week for 3 months before being discharged from the hospital. The second group will be treated with calcium and vitamin D and the injectable parathyroid hormone branded synapar ;0.08 cc daily in the abdomen for 3 months. The third group of patients from patients admitted to the service of other orthopedic professors who receive only 1200 milligrams of calcium daily and vitamin D 800 units. Then they will be followed up after the discharge. After 1 month and 3 months, patients will be followed up by telephone over their medications and their acceptance capacity, as well as the side effects of drugs and the incidence of fracture. Patients will also be requested at week 4 and 8 and 12, and after surgery to check the amount of restoration of fracture by radiography. Also, in follow-up 3 months later, bone density measurement will be done at the same center by the same technician. . And if the patient situation does not improve, the patient's will continue the treatment according to bone Densimetry.

Participants/Inclusion and exclusion criteria

major inclusin and exclusion criteria: Patients Aged over 50 years, with a sudden fracture of the wrist, vertebra or hip with Tscore less than 2.5 - who have undergone a Corrective surgical procedure, and Do not take anti-osteoporosis drugs including bisphosphonate, calcitonin, raloxifene, and parathyroid hormone over the past 6 months before fracture were included; Patients who have Previous history of osteoporotic fractures, Multiple trauma, Cancer, Other diseases requiring aggressive, corticosteroid, or immunosuppressive therapy and Selective arthroplasty were excluded

Intervention groups

Intervention group one: 1200 mg daily calcium, vitamin D-800 units plus parathyroid hormone injections branded sinopar Intervention group two: daily 1200 mg calcium, vitamin D 800 units plus alendoronitis made with a dose of 70 mg Control group: daily calcium group 1200 mg, vitamin D 800 units

Main outcome variables

The rate of fracture restoration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160830029603N6**
Registration date: **2018-01-24, 1396/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-24, 1396/11/04**
Update count: **0**

Registration date

2018-01-24, 1396/11/04

Registrant information

Name

Masoud Shayestehazar

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of anti-osteoporosis therapies on the repair of osteoporotic fractures in patientss admitted to the orthopedic ward

Public title

Comparison of the effect of anti-osteoporosis therapies on the repair of osteoporotic fractures

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 50 years old Patients with a sudden fracture of the wrist, vertebra or hip with Tscore less than 2.5 - who have undergone a Corrective surgical procedure Do not take anti-osteoporosis drugs including bisphosphonate, calcitonin, raloxifene, and parathyroid hormone over the past 6 months before fracture

Exclusion criteria:

Previous history of osteoporotic fractures Multiple trauma Cancer Other diseases requiring aggressive, corticosteroid, or immunosuppressive therapy Selective arthroplasty

Age

From **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Random by using Random NumbersTable

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, First of Vali Asr HWY., Joibar Junction, Emam Sq.

City

sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2016-10-31, 1395/08/10

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.95.2767

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M80

ICD-10 code description

Osteoporosis with current pathological fracture

Primary outcomes

1

Description

The rate of fracture restoration

Timepoint

the assessment of fracture restoration in weeks 4, 8 and 12 after surgery

Method of measurement

Radiography

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Calcium and Vitamin D with

parathyroid hormone branded Sinopar

Category

Treatment - Drugs

2

Description

Second Intervention group: Calcium and Vitamin D with Alendoronite made at a dose of 70 milligrams

Category

Treatment - Drugs

3

Description

Control group: Calcium and Vitamin D

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr Masoud Shayestehazar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Ahmad Ali Enayati

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Deputy of Research and Technology of Mazandaran University of Medical Science, moalem Sq., Moalem St., Sari

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Saber Joor Ebrahimian

Position

orthopedic resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Doctor Masoud Shayesteh Azar

Position

Hip Surgery Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Doctor Saber Joor Ebrahimian

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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