Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Cinnopar on bone density, serum phosphorus and calcium levels in postmenopausal women with osteoporosis

Protocol summary

Summary

The purpose of this study is to examine the effect of the injectable Cinnopar on the process of sickness , the rate of fractures, bone density, calcium level and serum phosphor in postmenopausal women with osteoporosis. Design:This study is a singel blinded clinical trial which will be conducted on postmenopausal women with osteoporosis in Imam khomeini hospital in Sari-Iran. The sample size is computed to be 30 clients in each group according to previous studies, and 95% confidence level. Methods and materials: Approval is obtained from the Mazandaran University of Medical Sciences. Patients are recruited into the study by means of a convenience sampling method, and then randomly divided into two groups of experimental and control. All data will be collected by one of the researchers involved in this study. If patients give consent to participate in the study, the socio-demographic data and clinical data will be first gathered by a questionnaire. Then the samples by the orders of their entry to the experiment using Rand Between function in Excel software will be randomly assigned into intervention and control groups. Clinical data are recorded using a questionnaire, including bone densitometry before treatment and six months after treatment, serum levels of calcium, vitamin D, alkaline phosphatase and phosphorus before treatment and six months after treatment. Inclusion criteria: Postmenopausal women (aged 45 to 75 years old) diagnosed with osteoporosis by densitometry via Dexa(dual energy Xray absorptiometry). Exclusion criteria: Women with a history of taking corticosteroids or any other medications which cause osteoporosis. Intervention:experimental group receive daily 8/0 unit hypodermic insulin syringe from Cinnopar for six month.and daily receive 1000mg calcium and 400 unit edible vitaminD tablets for six month. control group daily receive 1000mg calcium and 400 unit edible vitaminD tablets for six month. The main outcome variables:Bone density; serum calcium and phosphorus level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016083029603N1**
Registration date: **2017-06-03, 1396/03/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-03, 1396/03/13

Registrant information

Name
Masoud Shayestehazar
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Cinnopar on bone density, serum phosphorus and calcium levels in postmenopausal women with osteoporosis

Public title
The effect of cinnopar (teriparatide) in post-menopausal women with osteoporosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Postmenopausal women (aged 45 to 75 years old) diagnosed with osteoporosis by densitometry via Dexa(dual energy Xray absorptiometry); who do not have any history of treatment for osteoporosis; and consent to participate in the study were recruited into the study. Exclusion criteria: Women with a history of taking corticosteroids or any other medications which cause osteoporosis ; hyperparathyroidism.

Age
From **45 years** old to **75 years** old

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Science

Street address
Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moalem Sq., Moalem St., Sari

City
Sari

Postal code

Approval date
2016-03-15, 1394/12/25

Ethics committee reference number
IR.MAZUMS.REC.94-1752

Health conditions studied

1

Description of health condition studied
Osteoporosis

ICD-10 code
M80.0

ICD-10 code description
Osteoporosis in postmenopausal women

Primary outcomes

1

Description
bone density

Timepoint
Before treatment and six months after treatment

Method of measurement
densitometry test through Dexa(dual energy Xray absorptiometry

2

Description
serum levels of calcium

Timepoint
Before treatment and six months after treatment

Method of measurement
blood test

3

Description
phosphor level

Timepoint
Before treatment and six months after treatment

Method of measurement
blood test

Secondary outcomes

1

Description
Fractures

Timepoint
One year

Method of measurement
Radiography

Intervention groups

1

Description
experimental group receive daily 8/0 unit hypodermic

insulin syringe from Cinnopar for six month. and daily receive 1000mg calcium and 400 unit edible vitaminD tablets for six month

Category

Treatment - Drugs

2

Description

control group daily receive 1000mg calcium and 400 unit edible vitaminD tablets for six month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

University Hospitals of Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Masoud Shayesteh Azar

Street address

Emam Khomeini Hospital, Amir Mazandarani St., Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Ahmad Ali Enayati

Street address

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

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Masoud Shayesteh Azar

Position

Hip Surgery Fellowship

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Doctor Zeinab Andarkhora

Position

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty