

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 phosphorus in postmenopausal women with osteoporosis. Design: This study is a single-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 X-ray 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 months and daily receive 1000mg calcium and 400 unit edible vitamin D tablets for six months. Control group daily receive 1000mg calcium and 400 unit edible vitamin D tablets for six months. 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

Country

Iran (Islamic Republic of)

Phone

+98 11 3304 4859

Email address

shayestehazar@mazums.ac.ir

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 X-ray 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 X-ray 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**Street address**

Mazandaran University of Medical Sciences, First of Vali Asr Hwy., Joibar 3way, Emam Sq., Sari

City

Sari

Postal code

4815733971

Phone

+1 133377169

Fax**Email**

shayestehazar@mazums.ac.ir

Web page address**Person responsible for scientific 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**Street address**

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

City

Sari

Postal code

4815733971

Phone

+98 11 3337 7169

Fax**Email**

shayestehazar@mazums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Zeinab Andarkhora

Position**Other areas of specialty/work****Street address**

Ema Khomeini Hospital, Amir Mazandarani St., Sari

City

Sari

Postal code

48166_33131

Phone

+98 11 3337 7169

Fax

Email

orthopedics@mazums.ac.ir

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