Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparing the effects of recombinant form of human PTH and the Brand type (Forteo) in improving Bone Mineral Density in patients having osteoporosis

Protocol summary

Summary

Losing bone density as a result of osteoporosis can not be fully recovered by using oral method of treatment and the only remedy that is able to recover the lost bone mass, is recombinant form of human parathyroid hormone. The present study is carried out to assess treatment effects of recombinant form of human PTH compared to its brand type in a randomized double-blind clinical trial with two parallel groups. Patients are menopause women aged 45-75 years old who are under treatment and have severe osteoporosis, the severity of osteoporosis is determined by bone mass densitometry (DEXA method) and history of patients. In each group, patients receive daily single dose of subcutaneous recombinant form of PTH (1-34) or brand type . Data regarding bone mass densitometry are gathered in a fixed center by a similar technique of DEXA method before and 6 months after treatment and T-Scores that are related to lumbar vertebra, neck of femur, and total hip are considered as target points in treatment. Bone turn over markers are also measured at baseline, one, three and six months after treatment. A questionnaire including demographic data and risk factors for losing bone density is filled out for every patient. After encoding, data will be entered in SPSS software and finally will be analyzed.

General information

Acronym

rhPTH vs FORTEO

IRCT registration information

IRCT registration number: **IRCT138810121414N5**
Registration date: **2010-09-22, 1389/06/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-09-22, 1389/06/31

Registrant information

Name

Bagher Larijani

Name of organization / entity

Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Cinnagen Biotechnology

Expected recruitment start date

2011-02-01, 1389/11/12

Expected recruitment end date

2012-10-10, 1391/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of recombinant form of human PTH and the Brand type (Forteo) in improving Bone Mineral Density in patients having osteoporosis

Public title

Comparing the effects of recombinant form of human

PTH and the Brand type (Forteo) in improving Bone Mineral Density in patients having osteoporosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients are menopause women aged 45-75 who have following conditions: A) T-score less than -3 in lumbar vertebras, neck of femur or total hip in bone mass densitometry by DEXA method without evidences of fracture with low trauma due to osteoporosis. B) T-score less than -2.5 in one of mentioned regions due to osteoporosis with low trauma in vertebras or limbs. C) Women aged 55 and over with T-score less than -2.5 in one of regions of lumbar vertebras, neck of femur or total hip in bone mass densitometry by DEXA method without evidence of fracture with low trauma due to osteoporosis. D) Women aged 55 and over with T-score less than -2 at one of mentioned regions with history of fracture due to osteoporosis and low trauma in vertebras or limbs. Exclusion criteria: A) Rejecting to take part in the study and anticipating lack of cooperation during treatment and follow up periods. B) History of taking bone resorption inhibitor medications such as; Bisphosphanates at least for four weeks. C) Having a disease or being under treatment that interacts with bone metabolism and disrupts treatment process like auto-immune diseases, long term taking of Corticosteroid, chemotherapy or radiotherapy, epilepsy under treatment. D) Hypercalcemia above 10 mg/dl or hypercalceuria with ratio of Uca/Ucr>0.35, history of receiving PTH or stransium, history of urinary stones, advanced stage of liver or kidney disorders, intestinal malabsorbtion, hyper& hypoparathyroidism, hyperthyroidism, history of cancer in 5 years before the first visit, hyperuricemia and gout, lactation.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Endocrine & Metabolism Research Institute

Street address

North Karegar St, Dr. Shariati Hospital

City

Tehran

Postal code

1411413137

Approval date

empty

Ethics committee reference number

E-0015

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M81.0, M80

ICD-10 code description

Osteoporosis with and without pathological fracture

Primary outcomes

1

Description

Bone markers

Timepoint

1st, 3rd and 6th month of the study

Method of measurement

DEXA

2

Description

Bone mineral density (BMD)

Timepoint

At the beginning and 6 month after the start of study

Method of measurement

DXA

Secondary outcomes

1

Description

Fragility fracture prevention

Timepoint

6 mounths after the start of the study

Method of measurement

thoracolumbar & Hip radiography

Intervention groups

1

Description
Intervention group: Patients will receive daily dose of 20µg Cinagen rhPTH subcutaneously for 6 month. PTH will be prescribed in the morning via subcutaneous injection pen. Cartridges will be changed every 2 weeks
Category
Treatment - Drugs

2

Description
Control group: Patients will receive daily dose of 20µg FORTEO subcutaneously for 6 month. FORTEO will be prescribed in the morning via subcutaneous injection pen. Cartridges will be changed every 2 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine & Metabolism Research Institute
Full name of responsible person
Dr. Ramin Heshmat
Street address
North Karegar St, Dr. Shariati Hospital, Endocrine & Metabolism Research Institute
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cinagen biotechnology
Full name of responsible person
Dr. Mahboodi
Street address
No.56, Azimi Alley, Phase 1, Ekbatan Complex
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cinagen biotechnology
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Endocrine & Metabolism Research Istitute, Tehran University of Medical Sciences
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Person responsible for updating data

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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