

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

High dose vitamin D supplement versus conventional dose in women over 50 years with osteoporosis and osteopenia (T Score < -1)

Protocol summary

Summary

Background: Vitamin D (vitD) deficiency is very common in Iran. According to several study on vitD doses to achieve the optimal level of serum 25(OH)D, we compare high dose vitD with conventional dose, in elderly osteopenic women. Methods: this study was a one year randomized clinical trial, in Endocrine & Metabolism Research Center of Shariati hospital in 2008-9. The subjects were osteopenic women over 50 years who refer to bone densitometry laboratory. They were received either (group P) 50,000u vitD3 weekly for 3 month then monthly for another 9 month, or (group M) 800u vitD3 daily for one year. 1000 mg calcium carbonate were given to both groups. Serum 25(OH)D, Calcium, Phosphor, PTH was checked at base, 3rd, 6th and 12th month. 24h Urine for calcium were collected before and at the end of trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106126780N1**

Registration date: **2012-11-21, 1391/09/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-21, 1391/09/01

Registrant information

Name

Alireza Bagheri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2366

Email address

bagheri_a@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Vice chancellor for research, Endocrine & metabolism Research Institute

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2009-05-05, 1388/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

High dose vitamin D supplement versus conventional dose in women over 50 years with osteoporosis and osteopenia (T Score < -1)

Public title

Comparison of conventional dose with high dose vitamin D in osteoporotic or osteopenic (T Score < -1) women over 50 yrs referring to Shariati Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Outpatient women over 50 years old who have (T score < -1) in any site on their BMD at Shariati Hospital BMD laboratory. Exclusion Criteria: Vitamin D supplementation in the last 6 months; Glucocorticoid use in last 3 months; Use of Levothyroxine, anticonvulsant drugs, Lithium, Estrogen, Progesterone, Teriparatide, Cyclosporine; History of : Hyperparathyroidism, Hyperthyroidism, Romatoid

Arthritis, Ankylosing Spondylitis, Malignancy, CKD (GFR<30), Premature Ovarian Failure.

Age

From **50 years** old to **90 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

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 and Metabolism Research Institute

Street address

5th floor, Shariati Hospital, North karegar

City

Tehran

Postal code

PO Box: 1411713135

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

00202

Health conditions studied

1

Description of health condition studied

osteoporosis

ICD-10 code

M81.0

ICD-10 code description

Postmenopausal osteoporosis

2

Description of health condition studied

Vitamin D deficiency

ICD-10 code

E55

ICD-10 code description

Vitamin D deficiency

Primary outcomes

1

Description

serum 25(OH) D level

Timepoint

at base, 3rd, 6th and 12th month

Method of measurement

ELISA kits Immunodiagnostic Systems Ltd (IDS), Boldon,UK with 5 nmol/L sensitivity

Secondary outcomes

1

Description

Serum Ca

Timepoint

at base, 3rd, 6th and 12th month

Method of measurement

MTB assay, mg/dl

2

Description

Serum P

Timepoint

at base, 3rd, 6th and 12th month

Method of measurement

UV assay, mg/dl

3

Description

Serum PTH

Timepoint

at base, 3rd, 6th and 12th month

Method of measurement

ELISA kits Immunodiagnostic Systems Ltd (IDS), Boldon,UK , with 0/06 pmol/L sensitivity

4

Description

24 Hours Urine for Calcium

Timepoint

at base and 12th month

Method of measurement

MBT assay, mg/dl

Intervention groups

1

Description

50,000u vitamin D3 pearl, weekly for 3 month then monthly for another 9 month

Category

Treatment - Drugs

2**Description**

control : 400 iu vitamin D3 tablet twice a day for one year

Category

Treatment - Other

Recruitment centers1**Recruitment center****Name of recruitment center**

BMD Clinic in Shariati Hospital

Full name of responsible person

Alireza Bagheri, Internal Medicine resident

Street address

Shariati Hospital, North Karegar

City

Tehran

Sponsors / Funding sources1**Sponsor****Name of organization / entity**Endocrine and Metabolism Research Institute, Tehran
University of Medical Sciences**Full name of responsible person**

Mohamadreza Amini

Street address

5th floor, Shariati Hospital, North Karegar

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceEndocrine and Metabolism Research Institute, Tehran
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**

Endocrinology and Metabolism Research Institute

Full name of responsible person

Akbar Soltani

PositionEndocrinologist, associated professor, Tehran
University of Medical Sciences**Other areas of specialty/work****Street address**

5th floor, EMRI, , Shariati Hospital, North Kargar Ave

City

Tehran

Postal code

1411413137

Phone

+98 21 8026 9023

Fax**Email**

soltania@sina.tums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Endocrinology and Metabolism Research Institute

Full name of responsible person

Hamidreza Aghai Meybodi

Position

Endocrinologist, Assistant Professor

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

5th floor, EMRI, Shariati Hospital - North Kargar ave

City

Tehran

Postal code

1411413137

Phone

+98 21 8822 0037

Fax**Email**

hraghai@tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Alireza Bagheri

Position

Internal Medicine resident

Other areas of specialty/work**Street address**Department of Internal Medicine, Shariati Hospital,
North Karegar**City**

Tehran

Postal code

۱۴۱۱۷۱۳۱۳۵

Phone

+98 21 8490 2923

Fax

+98 21 8490 2366

Email

bagheri_a@razi.tums.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