

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 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

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##### 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 centers****1****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**

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**Sponsors / Funding sources****1****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 source**Endocrine 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

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

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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