Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effects of monthly and bimonthly consumption of 50 000 units of oral vitamin D3 on serum levels of 25-OHD, iPTH, calcium and other bone markers and comparison of the results with placebo group in 210 healthy school children of Taleghan

Protocol summary

Summary

The present study was designed to evaluate the effects of monthly and bimonthly consumption of 50000 units of oral D3 on 210 healthy students who did not take any medications affecting bone metabolism during during fall and winter 2007-2008 in Taleghan. The participants were assigned to 3 groups to receive 50000 units vitamin D3 monthly, 50000 units vitamin D3 bimonthly, or placebo. Serum levels of 25-OHD, i PTH, calcium and other bone markers were evaluated at the beginning, middle and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711231681N1**
Registration date: **2010-08-25, 1389/06/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-08-25, 1389/06/03

Registrant information

Name

Ali Asghar Mirsaeid Ghazi

Name of organization / entity

Research institue for endocrine sciences, Shahid Beheshti University of Medical Sciences (MC)

Country

Iran (Islamic Republic of)

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ghazi@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences (MC)

Expected recruitment start date

2007-07-20, 1386/04/29

Expected recruitment end date

2009-03-20, 1387/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of monthly and bimonthly consumption of 50 000 units of oral vitamin D3 on serum levels of 25-OHD, iPTH, calcium and other bone markers and comparison of the results with placebo group in 210 healthy school children of Taleghan

Public title

Effects of different doses of oral Cholecalciferol on serum 25-OHD,PTH, Calcium,and bone markers during Fall and Winter in school children of Taleghan

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All healthy active students. Exclusion criteria: Those with disorders affecting bone metabolism or taking supplements or drugs affecting bone metabolism.

Age

From **14 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Institute for Endocrine Sciences,Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yemen Ave.,Parvane ST.,No 24

City

Tehran

Postal code

1985717413

Approval date

2008-02-05, 1386/11/16

Ethics committee reference number

222

Health conditions studied

1

Description of health condition studied

Status of vitamin D in school children

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

Primary outcomes

1

Description

serum levels of 25-OHD

Timepoint

at the begining, middle, and end of the study

Method of measurement

RIA

Secondary outcomes

1

Description

serum levels of bone specific alkaline phosphatase

Timepoint

At the beginning, middle, and the end of the study

Method of measurement

RIA

2

Description

serum levels of osteocalcin

Timepoint

samples were taken at the begining, middle, and end of the study

Method of measurement

RIA

3

Description

serum levels of Calcium.

Timepoint

At the beginning, middle, and the end of the study

Method of measurement

RIA

4

Description

serum levels of iPTH

Timepoint

At the beginning, middle, and the end of the study

Method of measurement

RIA

5

Description

24 hour urine c-telopeptide

Timepoint

At the beginning, middle, and the end of the study

Method of measurement

RIA

Intervention groups

1

Description

50 000 units of oral vitamin D3 monthly during 6 months.

Category

Treatment - Drugs

2

Description
Placebo monthly, similar to the real drug in shape for 6 months
Category
Placebo

3

Description
50 000 units of oral vitamin D3 bimonthly during 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
highschools of Shahrak, centre of Taleghan
Full name of responsible person
Mr. Noroozi
Street address
Shahrak, Taleghan,
City
Taleghan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Institute for Endocrine Sciences,Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali A.M. Ghazi MD
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No 24, Parvane ST., Yemen Ave., Velenjak,
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Institute for Endocrine Sciences,Shahid Beheshti 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
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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