Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of different doses of oral Cholecalciferol on serum1-25(OH)D during Fall and Winter in 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 Serum levels of 1-25(OH)D and comparison of the result with placebo in 210 healthy students who did not take any medications affecting bone metabolism 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 1-25(OH)D were evaluated at the beginning, middle and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009131681N2**
Registration date: **2010-09-15, 1389/06/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-09-15, 1389/06/24

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)

Phone

+98 21 2240 9309

Email address

ghazi@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2007-07-20, 1386/04/29

Expected recruitment end date

2008-03-20, 1387/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of different doses of oral Cholecalciferol on serum1-25(OH)D during Fall and Winter in school children of Taleghan

Public title

vitamin D status in school children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: healthy active students Exclusion criteria: Presence of disorders affecting bone metabolism, 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
Shahid Beheshti University of Medical Sciences
Street address
Parvane ST., Yemen Ave., Velenjak,
City
Tehran
Postal code
Approval date
2010-08-29, 1389/06/07
Ethics committee reference number
88

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 1-25(OH)D
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
IRA

2

Description
serum levels of Calcium
Timepoint
At the beginning, middle, and the end of the study
Method of measurement
IRA

3

Description
serum levels of 25-OHD
Timepoint
at the begining, middle, and 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
IRA

5

Description
serum levels of osteocalcin
Timepoint
At the begining, middle, and end of the study
Method of measurement
IRA

6

Description
24 hour urine c-telopeptide
Timepoint
At the beginning, middle, and the end of the study
Method of measurement
IRA

Intervention groups

1

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

2

Description
50 000 units of oral vitamin D3 bimonthly during 6 months

Category
Treatment - Drugs

3

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

Recruitment centers

1

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

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali A.M. Ghazi MD
Street address
Parvane ST., Yemen Ave., Velenjak
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali A.M.Ghazi MD
Position
Professor of Internal Medicine and Endocrinology
Other areas of specialty/work
Street address
Taleghani Hospital
City
Tehran
Postal code
1985717413
Phone
+98 21 2240 9309
Fax
Email
ghazi@endocrine.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali A.M.Ghazi MD
Position
Professor of Internal Medicine and Endocrinology
Other areas of specialty/work
Street address
Taleghani Hospital
City
Tehran
Postal code
Phone
+98 21 2240 9309
Fax
Email
ghazi@endocrine.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Siavash M.Ghazi MD
Position
MD
Other areas of specialty/work
Street address
City
Tehran
Postal code
Phone
+98 21 8808 7505
Fax
Email
siavashmsgh@gmail.com
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