Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of 1000 and 50000 IU vitamin D supplement on serum calcium and vitamin D in adults with vitamin D deficiency

Protocol summary

Study aim
The comparison effect of 1000 and 50,000 IU vitamin D on serum calcium and vitamin D on vitamin D-deficient adults
Design
Block randomization, double blind, 120 participant
Settings and conduct
each participant is given both 1000IU vitamin D or its placebo and 50000IU vitamin D or it's placebo in order to make the participant blind
Participants/Inclusion and exclusion criteria
people who have not used calcium and vitamin D supplements in the last 2 months lack of liver and kidney failure lack of steatorrhea lack of atherosclerosis lack of medications that affect vitamin D metabolisms, such as parathormone, estrogen, and calcitonin lack of sarcoidosis, hyperparathyroidism, renal diseases and histoplasmosis having a light or moderate physical activity willingness to cooperate Those whose serum vitamin D is below 30 ng/ml
Intervention groups
vitamin D deficient subjects were divided into 3 groups: first those who received 1000 IU/day vitamin D plus 50000 IU/month placebo, second group was those who received 50000 IU/month vitamin D besides 1000IU/day vitamin D placebo and the third one was given 1000 IU/day and 50000 IU/day vitamin D placebo.
Main outcome variables
Vitamin D serum level

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180214038730N1**
Registration date: **2018-05-30, 1397/03/09**
Registration timing: **retrospective**
Last update: **2018-05-30, 1397/03/09**
Update count: **0**
Registration date
2018-05-30, 1397/03/09

Registrant information
Name
Tahereh Ranjbar
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-15, 1396/11/26
Expected recruitment end date
2018-04-19, 1397/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of 1000 and 50000 IU vitamin D supplement on serum calcium and vitamin D in adults with vitamin D deficiency

Public title
Effect of 1000 and 50,000 IU vitamin D on serum calcium and vitamin D
Purpose
Other
Inclusion/Exclusion criteria

Inclusion criteria:
having light or moderate physical activity willingness to cooperate those whose serum vitamin D were below 30 ng/ml in screening
Exclusion criteria:
people who have used calcium and vitamin D supplements in the last 2 months having liver and kidney failure having Steatorrhea having atherosclerosis using medications that affect vitamin D metabolism, such as parathormone, estrogen and calcitonin having sarcoidosis, hyperparathyroidism, renal diseases and histoplasmosis

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
block randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
each participant is given both 1000IU vitamin D or its placebo and 50000IU vitamin D or it's placebo in order to make the participant blind

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
7th floor- Central Building of Shiraz University of Medical Sciences- Zand Avenue

City
Shiraz

Province
Fars

Postal code
71345-1978

Approval date
2017-12-10, 1396/09/19

Ethics committee reference number
IR.SUMS.REC.1396.123

Health conditions studied

1

Description of health condition studied
vitamin D deficiency

ICD-10 code
E55

ICD-10 code description
Vitamin D deficiency

Primary outcomes

1

Description
serum vitamin D level

Timepoint
at the beginning(before intervention), 61st day after intervention

Method of measurement
Autoanalizer device

Secondary outcomes

1

Description
parathyroid hormones

Timepoint
before the intervention , 61st day after intervention

Method of measurement
auto-analyser device

2

Description
serum calcium level

Timepoint
before the intervention , 61st day after intervention

Method of measurement
auto-analyser device

3

Description
serum phosphorus level

Timepoint
before the intervention , 61st day after intervention

Method of measurement
auto-analyser device

4

Description

fibroblast growth factor 23

Timepoint

before the intervention , 61st day after intervention

Method of measurement

ELISA method

Intervention groups

1

Description

first intervention group: 1000 IU/day vitamin D and placebo of 50000 IU/month vitamin D

Category

Treatment - Other

2

Description

second intervention group: 50000 IU/month vitamin D and placebo of 1000 IU/day vitamin D

Category

Treatment - Other

3

Description

Control group:1000 IU/day and 50000 IU/day vitamin D placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Eram Student Dorm Collection

Full name of responsible person

Ali Ahmadi

Street address

Eram Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Masoume Akhlaghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available