

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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 its 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

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1005

Email address

tranjbar@sums.ac.ir

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

Autoanalyzer 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ali poust forush fard

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

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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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Person responsible for scientific

inquiries

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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