

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison the effect of oral vitamin D on serum level of 25(OH) vitamin D in two groups of healthy people with vitamin D deficiency with a level more and less than 10 ng/ml

Protocol summary

Summary

This is a clinical trial aimed to compare the effect of oral vitamin D on serum level of 25(OH) vitamin D in two groups of healthy people with vitamin D deficiency with a level more and less than 10 ng/ml. Study sample consists of 80 persons with a vitamin D level of less than 30 ng/ml and without clinical manifestations. Inclusion criteria are age of 20-40 years and having vitamin D level of less than 30 ng/ml and exclusion criteria are having renal or hepatic diseases, pregnancy or breastfeeding, using steroids or anticonvulsant drugs, using calcium or vitamin D3 supplements during last 6 months, history of hypercalcemia, sarcoidosis, active renal stone or using bisphosphonates. After inclusion in the study, the people will be grouped by their gender into male and female groups. Based on their 25(OH) vitamin D level, people in each group will be further subgrouped into a group with a vitamin D level less than 10 ng/ml and a group with a vitamin D level between 10 and 30 ng/ml. All the people will receive 50000 I/U per week oral vitamin D3 for 8 weeks. Then, serum level of 25(OH) vitamin D will be measured at the end of the third month and the mean changes in its serum level will be calculated based on body weight, gender and based on initial 25(OH) vitamin D level. In these people, the mean serum level of PTH will be also compared before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042433630N1**

Registration date: **2017-05-20, 1396/02/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

Name

Mahdie Khodadoost

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5715

Email address

m.khodadoost@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-20, 1396/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of oral vitamin D on serum level of 25(OH) vitamin D in two groups of healthy people with vitamin D deficiency with a level more and less than 10 ng/ml

Public title

The effect of oral vitamin D on serum level of 25(OH) vitamin D

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 20-40 years; having vitamin D level of less than 30 ng/ml. Exclusion criteria: having renal or hepatic diseases; pregnancy or breastfeeding; using steroids or anticonvulsant drugs; using calcium or vitamin D3 supplements during last 6 months; history of hypercalcemia; sarcoidosis; using bisphosphonates.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City

Zahedan

Postal code**Approval date**

2017-03-05, 1395/12/15

Ethics committee reference number

IR.ZAUMS.REC.1395. 277

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 level of 25(OH) vitamin D

Timepoint

At the start of the study, three months after using vitamin D

Method of measurement

Measurement by laboratory

Secondary outcomes

empty

Intervention groups**1****Description**

All the people under study: 50000 I/U per week oral vitamin D3 for 8 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Ebne Abi Taleb Hospital

Full name of responsible person

Mahdie Khodadoost

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Khalije Fars Blv, Zahedan

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Zahedan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Hoshang Rafighdoost

Street address

Vice chancellor for research, Zahedan University of Medical Sciences campus, Jannat Blv, Zahedan

City

Zahedan

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Zahedan 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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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