Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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(OH0 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
Street address
Khalije Fars Blv, Zahedan
City
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

Zahedan University of Medical Sciences

Full name of responsible person

Mahdie Khodadoost

Position

Internal medicine resident

Other areas of specialty/work

Street address

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

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Associate Professor

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Person responsible for updating data

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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