

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of serum levels of 25-hydrovitamin D after taking oral or sublingual vitamin D in medical students with insufficient serum vitamin D

Protocol summary

Study aim

Comparison of the efficacy of oral versus sublingual vitamin D supplementation on serum 25-hydroxyvitamin D levels in medical students with vitamin D deficiency

Design

A phase 3, randomized, double-blind, placebo-controlled, parallel-group clinical trial conducted on 60 patients. Randomization will be performed using R software.

Settings and conduct

This study is a double-blind randomized clinical trial with parallel groups, conducted on 60 male medical students at Zahedan University of Medical Sciences with vitamin D levels below 30 ng/mL. Participants will be randomly allocated into two equal groups to receive either oral or sublingual vitamin D supplementation at a dose of 50,000 units weekly for 8 weeks. Primary outcomes include changes in serum levels of 25-hydroxyvitamin D, calcium, phosphorus, and parathyroid hormone at predefined time points. Data will be analyzed and compared using statistical software.

Participants/Inclusion and exclusion criteria

Inclusion Criteria :Male medical students at Zahedan University of Medical Sciences-Serum 25-hydroxyvitamin D level below 30 ng/mL-Age between 18 and 40 years-Willingness to participate and provide signed informed consent- No intake of vitamin D or calcium supplements within the past 3 months. Exclusion Criteria : Chronic renal, hepatic, or gastrointestinal diseases -Use of medications affecting vitamin D metabolism -History of hypercalcemia or kidney stones- Allergy to vitamin D or any components of the supplements.

Intervention groups

The first intervention group will receive 50,000 IU of vitamin D supplement orally on a weekly basis. The second intervention group will receive the same dosage administered sublingually each week. Both groups will follow this treatment regimen for 8 weeks and undergo

periodic monitoring.

Main outcome variables

Change in serum 25-hydroxyvitamin D levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250904067125N1**

Registration date: **2025-09-14, 1404/06/23**

Registration timing: **prospective**

Last update: **2025-09-14, 1404/06/23**

Update count: **0**

Registration date

2025-09-14, 1404/06/23

Registrant information

Name

mahpari zafarzamen

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5725

Email address

dr.zafarzamen@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-21, 1404/07/29

Expected recruitment end date

2026-03-18, 1404/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of serum levels of 25-hydrovitamin D after taking oral or sublingual vitamin D in medical students with insufficient serum vitamin D

Public title

Comparison of the Effect of Oral versus Sublingual Vitamin D3 Supplementation on Serum 25-Hydroxyvitamin D Levels in Medical Students with Vitamin D Deficiency: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being a medical student at Zahedan University of Medical Sciences. Aged between 18 and 30 years. Diagnosed with vitamin D deficiency, defined as a serum 25-hydroxyvitamin D level below 20 ng/mL. Willingness to participate and provision of signed informed consent. Not having taken any vitamin D or calcium supplements within the 3 months prior to the start of the study.

Exclusion criteria:

Presence of chronic diseases affecting vitamin D or calcium metabolism (e.g., renal or hepatic failure, hyperparathyroidism, sarcoidosis). Presence of malabsorption syndromes (e.g., celiac disease, Crohn's disease, ulcerative colitis). Use of medications known to interfere with vitamin D metabolism (e.g., anticonvulsants, systemic glucocorticoids, azole antifungals). History of hypercalcemia or calcium kidney stones. Pregnancy or lactation. Known hypersensitivity to vitamin D or any excipients in the study tablets. Unwillingness to continue cooperation or concurrent participation in another clinical trial.

Age

From **18 years** old to **30 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants who meet the inclusion criteria will be randomly assigned to one of the two intervention groups using a blocked randomization method, generated by random number software. The allocation sequence will be prepared by an independent colleague not involved in the screening or intervention process and

will be concealed in sequentially numbered, opaque, sealed envelopes. The principal investigator will open the corresponding envelope only after confirming the participant's eligibility and assigning them a study ID, thereby revealing the assigned intervention (oral or sublingual supplement). This procedure ensures that both the participants and the investigating researcher are blinded to the group assignment during the allocation process.

Blinding (investigator's opinion)

Double blinded

Blinding description

Based on whether the patient's visit invoice number is even or odd, the patient is assigned to either group A or B, and one of the two formulations (oral or sublingual) at a dose of 50,000 units is administered by the clinical caregiver. The patient has no information about the treatments received by others. The researcher, outcome assessor, and data analyst are only aware of the findings from groups A and B and have no knowledge of which drug formulation was administered in each group.

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

Medical Sciences Campus, Dr. Hessaby Square

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Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2024-10-12, 1403/07/21

Ethics committee reference number

IR.ZAUMS.REC.1403.281

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

Measurement of serum vitamin D levels at baseline and at the end of the eighth week

Method of measurement

Based on the measurement of serum 25-hydroxyvitamin D levels in the laboratory.

Secondary outcomes

1

Description

Serum vitamin D level

Timepoint

Measurement of serum vitamin D levels at baseline and at the end of the eighth week

Method of measurement

Based on the measurement of serum 25-hydroxyvitamin D levels in the laboratory.

Intervention groups

1

Description

Intervention Group 1: Patients in this group will receive one 50,000 IU vitamin D pearl (D-Vitin; manufactured by Zahravi Pharmaceutical Company) weekly for 8 weeks. Serum vitamin D levels will be remeasured at the end of the eighth week.

Category

Treatment - Drugs

2

Description

Intervention Group 2: Patients in this group will receive a sublingual form of vitamin D at a dose of 50,000 IU (manufactured by Zahravi Pharmaceutical Company). Serum vitamin D levels will be measured again at the end of the eighth week after treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Medicine, Zahedan University of Medical Sciences

Full name of responsible person

Mahpari Zafar Zamen

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Alireza Ansari Moghaddam

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Vice Chancellery for Research and Technology, Medical Sciences Campus, Zahedan University of Medical Sciences, Persian Gulf Boulevard, Zahedan, Iran.

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Mahpari Zafar Zamen

Position

Resident Assistant in Internal Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only the portion of data relevant to the main topic is displayed.

When the data will become available and for how long

Access period begins 6 months after the publication of results.

To whom data/document is available

Will only be accessible to researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used

There are no special requirements

From where data/document is obtainable

Please refer to Dr. Mahperi Zafar Zaman, Internal Medicine Department, Imam Ali Ibn Abi Talib Hospital, Zahedan.

What processes are involved for a request to access

data/document

Requests will be reviewed via email at
dr.zafarzaman@zaums.ac.ir and responded to in the

shortest possible time

Comments