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
City
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
Street address
Faculty of Medicine, Medical Sciences Campus, Zahedan University of Medical Sciences, Dr. Hessaby Square, Zahedan, Iran.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 992 981 7506
Email
Dr.zafarzamen@zaums.ac.ir
Web page address
https://med.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Alireza Ansari Moghaddam
Street address
Vice Chancellery for Research and Technology, Medical Sciences Campus, Zahedan University of Medical Sciences, Persian Gulf Boulevard, Zahedan, Iran.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2117
Email
Dr.zafarzamen@zaums.ac.ir
Web page address
https://research.zaums.ac.ir/
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

Street address
Medical Sciences Campus, Zahedan University of Medical Sciences, Persian Gulf Boulevard, Zahedan, Iran

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5770

Email
Dr.zafarzamen@zaums.ac.ir

Web page address
https://zaums.ac.ir/

Person responsible for scientific 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

Street address
Medical Sciences Campus, Zahedan University of Medical Sciences, Dr. Hessaby Square, Zahedan, Iran.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5570

Email
Dr.zafarzamen@zaums.ac.ir

Web page address
https://zaums.ac.ir

Person responsible for updating data

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

Street address
Medical Sciences Campus, Zahedan University of Medical Sciences, Dr. Hessaby Square, Zahedan, Iran.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5570

Email
Dr.zafarzamen@zaums.ac.ir

Web page address
https://zaums.ac.ir

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