Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of vitamin D3-fortified natural chewing gum's impact on students' serum 25(OH)D levels.

Protocol summary

Study aim

1- Determining the effect of consuming natural gum enriched with vitamin D3 on serum 25(OH)D levels in students of the Faculty of Health, Qazvin University of Medical Sciences 2- Determining the effect of consuming natural gum enriched with vitamin D3 on serum calcium levels 3- Determining the effect of consuming natural gum enriched with vitamin D3 on serum phosphorus levels 4- Determining the effect of consuming natural gum enriched with vitamin D3 on serum PTH hormone levels 5- If possible, producing natural gum enriched with vitamin D3

Design

A two-group clinical trial in which one group received natural gum enriched with vitamin D3 and the other group received vitamin D3 tablets, single-blinded because it is not known which patient may be placed in the gum or drug group, randomized with allocation software.

Settings and conduct

Sampling and isolating individuals with low serum 25OH D levels, then randomizing and donating pills or gum to groups, and taking blood after one month of use.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No underlying disease (diabetes, autoimmune diseases), kidney and cardiovascular diseases and insufficiency, digestive diseases and indigestion, no use of vitamin D supplements, no use of alcohol and drugs, use of drugs involved in fat absorption. Exclusion criteria: No continuation of the intervention due to illness or special events.

Intervention groups

Group receiving natural gum enriched with vitamin D3
Group receiving vitamin D3 tablets

Main outcome variables

Consumption of natural gum enriched with vitamin D3 affects serum levels of 25(OH)D. Consumption of natural gum enriched with vitamin D3 affects serum levels of calcium. Consumption of natural gum enriched with vitamin D3 affects serum levels of phosphorus. Consumption of natural gum enriched with vitamin D3 affects serum levels of PTH hormone.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251027067781N1**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-26, 1404/09/05**
Update count: **0**

Registration date

2025-11-26, 1404/09/05

Registrant information

Name
Arvin Shajeie
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3335 2653
Email address
a.shajeie@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D3-fortified natural chewing gum's impact on students' serum 25(OH)D levels.

Public title

Evaluation of the effect of consuming natural chewing gum fortified by vitamin D3 compared to vitamin D3 tablets

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Insufficient serum vitamin D3 levels Not pregnant No underlying disease (diabetes, autoimmune diseases) Kidney and cardiovascular diseases and failures Not taking vitamin D supplements Abstaining from alcohol and drugs Taking medications that affect fat absorption

Exclusion criteria:

pregnancy Taking vitamin D supplements Alcohol consumption

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of samples to two groups is done based on block random allocation. In this way, the sequence of samples will be determined with the help of Random Allocation Software Version 1.0.0. In order to conceal the random allocation process, the names of the groups will be placed in envelopes and these envelopes will be numbered and arranged in a box. The samples will be placed in one of the study groups in order according to the contents of the envelope.

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

Research Ethics Committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2025-03-08, 1403/12/18

Ethics committee reference number

IR.QUMS.REC.1403.492

Health conditions studied

1

Description of health condition studied

Vitamin D3 deficiency

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

Primary outcomes

1

Description

25(OH)D serum level

Timepoint

Before the start of the study and 14 and 30 days after starting to take the tablets and gum

Method of measurement

Testing of collected serum samples using ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Consumer of chewing gum enriched with vitamin D3

Category

Treatment - Other

2

Description

Control group: Vitamin D3 tablet user

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Qazvin University of Medical Sciences

Full name of responsible person
Arvin Shajeie

Street address
Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
15315-34199

Phone
+98 28 3335 2653

Fax
+98 28 3335 5162

Email
a.shajeie@gmail.com

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jiran Darou

Full name of responsible person
Weria Naseri

Street address
Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
34197-59811

Phone
+98 28 3335 2653

Fax
+98 28 3335 5162

Email
a.shajeie@gmail.com

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

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Jiran Darou company

Proportion provided by this source
30

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Razagh Mahmoudi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Food safety and Health

Street address
Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin,

City
Qazvin

Province
Qazvin

Postal code
34197-59811

Phone
+98 28 3335 2653

Fax
+98 28 3335 5162

Email
r.mahmodi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Razagh Mahmoudi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Food safety and Health

Street address
Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
34197-59811
Phone
+98 34 1975 9811
Fax
+98 28 3335 5162
Email
r.mahmodi@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Arvin Shajeie
Position
Student
Latest degree
Master
Other areas of specialty/work
Food safety and Health
Street address
Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Phone
+98 918 380 3601
Email
a.shajeie@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It is for clinical study only.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available