Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effect of consuming functional tomato paste enriched with vitamin D3 on serum levels in adults aged 20-60 years

Protocol summary

Study aim
The effect of consuming tomato paste enriched with vitamin D3

Design
This study is a single-arm trial and will examine the effect of consuming tomato paste enriched with 25-hydroxyvitamin D3 on the serum levels of 100 volunteers aged 20 to 60 years with appropriate eligibility criteria such as not having severe vitamin D deficiency and individuals with a BMI less than 30).

Settings and conduct
The study will be conducted in an appropriate setting, such as a research clinic or health center, to facilitate blood sampling and ensure close monitoring of participants. Nutritional Control: Ensuring participants consume a specified daily amount of tomato paste. This can be controlled by providing pre-measured packets to participants and recording the amount consumed. Monitoring and Supervision: The research team will include nutrition specialists, physicians, and laboratory technicians.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 20 and 60 years, Participants should not have chronic diseases, Participants should have low or normal serum vitamin D levels, but not higher than the optimal level, Participants should not have taken vitamin D supplements in the past 3 months, Consent to participate in the study Exclusion Criteria: Failure to consume vitamin D2-fortified food products, Failure to comply with the study conditions prescribed tomato paste, worsening of underlying diseases that affect the continuation of the study, Allergic reaction, Participant's decision to withdraw from the study at any stage.

Intervention groups
Consumption of vitamin D-fortified tomato paste

Main outcome variables
The concentration of vitamin D3 in the paste will remain constant. The rheological properties will not change. The sensory acceptance will not change. The concentration of vitamin D3 in the blood serum of the subjects will increase.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250115064387N1**
Registration date: **2025-04-17, 1404/01/28**
Registration timing: **prospective**

Last update: **2025-04-17, 1404/01/28**
Update count: **0**

Registration date
2025-04-17, 1404/01/28

Registrant information

Name
Ehsan Sadeghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 918 836 5313

Email address
e.sadeghi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-19, 1404/01/30

Expected recruitment end date
2026-04-19, 1405/01/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of consuming functional tomato paste enriched with vitamin D3 on serum levels in adults aged 20-60 years

Public title

Studying the effect of consuming functional tomato paste enriched with vitamin D3

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the participants should be between 20 and 60 years. The participants should not have chronic diseases. The participants should not have certain bone diseases such as severe osteoporosis. The participants' serum vitamin D levels should be low or within the normal range, but not higher than the optimal level. The participants should not have taken vitamin D supplements in the past 3 months. Consent to participate in the study should be obtained from the participants.

Exclusion criteria:

If the study conditions are not met by individuals. Inclusion of any additional intervention that affects serum vitamin D levels. Allergic reaction or intolerance to the ingredients in enriched tomato paste. Participant's decision to withdraw from the study at any stage.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

The informed consent form will be provided to the participants, and upon obtaining their consent, they will be evaluated based on the factors outlined in the study.Data collection will be conducted by colleagues and based on the results of laboratory tests and questionnaires. Participant visits will take place in a location where blood sampling and thorough follow-up of participants can be performed, such as a clinic.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Kermanshah University of Medical Sciences

Street address

Kermanshah - Shahid Beheshti Boulevard - Central Building of Kermanshah University of Medical Sciences.

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2025-01-01, 1403/10/12

Ethics committee reference number

50005142

Health conditions studied

1

Description of health condition studied

Vitamin D3 deficiency

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Change in Serum Vitamin D Levels:The change in serum 25-hydroxy vitamin D concentration between the beginning of the study and the end of the intervention period.This is the primary indicator of vitamin D status in the body and directly reflects the effect of the intervention.

Timepoint

Four months

Method of measurement

In this study, the effect of consuming tomato paste enriched with vitamin D3 on the serum levels of 100 volunteers aged 20 to 60 years with appropriate eligibility criteria such as not having severe vitamin D deficiency and people with a BMI less than 30 will be investigated. These people will consume the product for 4 months. It is possible to obtain 800 to 1000 units of vitamin D through foods fortified with this vitamin. In order to obtain this amount of vitamin and in accordance with the amount of vitamin D added to the product, it is considered to consume 100 grams of tomato paste per day. Finally, changes in serum vitamin D levels in people

will be determined using a blood test.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Consumption of vitamin D-fortified tomato paste.•
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital, Kermanshah
Full name of responsible person
Dr. Ehsan Sadeghi.
Street address
Kermanshah - End of Parastar Boulevard - Next to the Faculty of Medicine.
City
kermanshah
Province
Kermanshah
Postal code
5333 - 767427
Phone
+98 83 3427 6300
Fax
+98 83 3427 6300
Email
irhk @ kums.ac.ir
Web page address
https://imamreza.kums.ac.ir/fa/sitemap

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Zohra Rahimi
Street address
Kermanshah - Shahid Beheshti Boulevard - Central Building of Kermanshah University of Medical Sciences.
City
kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3838 4185
Fax
+98 83 3838 6835
Email
research_it@kums.ac.ir
Web page address
https://vc-research.kums.ac.ir/
Grant name
Grant code / Reference number
50005142
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Ehsan Sadeghi
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Food safety and Health
Street address
Kermanshah Province, Kermanshah City, Eythar Square, next to Farabi Hospital, Faculty of Nutrition and Food Industries.
City
kermanshah
Province
Kermanshah
Postal code
6719851552
Phone
+98 83 3710 2002
Fax
+98 83 3710 2002
Email
Nfst_school@kums.ac.ir
Web page address
https://nsft-school.kums.ac.ir/fa/contactus

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Ehsan Sadeghi

Position
professor

Latest degree
Specialist

Other areas of specialty/work
Food safety and Health

Street address
Kermanshah Province, Kermanshah City, Eythar Square, next to Farabi Hospital, Faculty of Nutrition and Food Industries.

City
kermanshah

Province
Kermanshah

Postal code
6719851552

Phone
+98 83 3710 2002

Fax
+98 83 3710 2002

Email
Nfst_school@kums.ac.ir

Web page address
https://nsft-school.kums.ac.ir/fa/contactus

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Ahsan Sadeghi

Position
professor

Latest degree
Specialist

Other areas of specialty/work
Food safety and Health

Street address
Kermanshah Province, Kermanshah City, Eythar Square, next to Farabi Hospital, Faculty of Nutrition and Food Industries.

City
kermanshah

Province
Kermanshah

Postal code
6719851552

Phone
+98 83 3710 2002

Fax
+98 83 3710 2002

Email
ehsan.sadeghi59@yahoo.com

Web page address
https://nsft-school.kums.ac.ir/fa/contactus

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Undecided - It is not yet known if there will be a plan to make this available

When the data will become available and for how long
Twelve months later.

To whom data/document is available
It is not yet known if there will be a plan to make this available

Under which criteria data/document could be used
It is not yet known if there will be a plan to make this available

From where data/document is obtainable
It is not yet known if there will be a plan to make this available

What processes are involved for a request to access data/document
It is not yet known if there will be a plan to make this available

Comments
I have no comments.