Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of vitamin D3 supplementation in people with vitamin D3 deficiency on fasting and 2hpp serum glucose and insulin and improvement of peripheral and visceral adipose tissue

Protocol summary

Summary

1) Few studies suggest the uncertainty of relation between vitamin D status, and insulin balance, as well as body composition. Finding this relationship in woman is more complex. This problem is probably more complex and wider in Iran due to the low vitamin D consumption and vitamin D deficiency. The main objective of this study was to determine the effect of vitamin D supplementation on body composition and insulin resistance. 2) Thus, in a clinical trial, 210 healthy people who are willing to collaborate on research project and have the serum vitamin D3 levels of less than 20 nanomoles per liter and 20 to 65 years of age will be enrolled. 3) The study design will be clinical trial. 4) people who have infectious diseases and inflammatory disorders of the thyroid gland; Digestive diseases such as stomach ulcers and inflammatory bowel disease; Pregnancy; Chronic use of glucocorticoid drugs, non-steroidal anti-inflammatory drugs, thyroxine, warfarin, D3 supplements; Injection of D3 Vitamin during the last year will be excluded. They will randomly assign to two groups. 5) The intervention group will receive a capsule of 50,000 IU of vitamin D for 8 weeks and the control group will receive placebo. 6) Blood samples, anthropometric measurements and body composition testing of individuals will be taken on arrival. All indexes at the beginning of the study will be repeated at the end of the eighth week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061622767N1**
Registration date: **2015-11-06, 1394/08/15**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-11-06, 1394/08/15

Registrant information

Name
Saeed Osati
Name of organization / entity
Shahid Beheshti University of Medical Sciences, International Branch
Country
Iran (Islamic Republic of)
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+98 21 4481 6488
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-11-23, 1394/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D3 supplementation in people with vitamin D3 deficiency on fasting and 2hpp serum glucose and insulin and improvement of peripheral and visceral adipose tissue

Public title
Effect of vitamin D3 supplementation in people with vitamin D3 deficiency on fasting and 2hpp serum glucose and insulin and improvement of peripheral and visceral adipose tissue
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria Willingness to cooperate in the research project; Healthy; Vitamin D3 serum levels less than 20 nmol per liter; Age 20 to 65 years old Exclusion criteria having infectious diseases and inflammatory disorders of the thyroid gland; Digestive diseases such as stomach ulcers and inflammatory bowel disease; Pregnancy; Chronic use of glucocorticoid drugs, non-steroidal anti-inflammatory drugs, thyroxine, warfarin, D3 supplements; Injection of D3 Vitamin during the last year -Diabetes
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **210**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Hemat, Tavanir cross road
City
Tehran
Postal code
Iran
Approval date
2015-09-18, 1394/06/27
Ethics committee reference number
1000/1175

Health conditions studied

1

Description of health condition studied
Healthy volunteer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum Vitamin D 3 Level
Timepoint
Before and 2 month after the intervention
Method of measurement
HPLC

2

Description
Serum Insulin Level
Timepoint
Before and 2 month after the intervention
Method of measurement
CLIA

3

Description
Fat Percent of body
Timepoint
Before and 2 month after the intervention
Method of measurement
DXA Lunar

Secondary outcomes

empty

Intervention groups

1

Description
During the intervention, participants in the intervention group will receive one 50,000- IU- Pearl of vitamin D 3 for 8 weeks (every week).
Category
Treatment - Drugs

2

Description
Participants in the control group will receive placebo for 8 weeks (every week).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Health conters under supervision of Shahid Beheshti University of Medical Sciences in Tehran

Full name of responsible person
Saeed Osati

Street address
No 11, Shaghayegh 13th, Imam Khomeini Ave, Hesarak, Poonak

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Saeed Osati

Street address
7th Floor, 2nd SBUMS Bldg, Next to Ayatollah Taleghani Hospital, Evin, Tehran.

City
Tehran

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, Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences.

Full name of responsible person
Saeed Osati

Position
PhD Caandidate

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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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