

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 21 4481 6488

###### Email address

saeedosati@sbmu.ac.ir

##### 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 centers 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 Candidate

#### Other areas of specialty/work

#### Street address

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

#### City

Tehran

#### Postal code

1477854351

#### Phone

+98 21 4481 6545

#### Fax

#### Email

saeedosati@sbm.ac.ir; saeedosati@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Majid Hajifaraji

#### Position

Director, National Nutrition & Food Technology Research Institute (NNFTRI) Dean, Faculty of Nutrition

#### Other areas of specialty/work

#### Street address

No 3, Baran Ave, West Arghavan, Farahzadi Blvd, Shahrak Qods

#### City

Tehran

#### Postal code

1981619573

#### Phone

+98 21 2236 0661

#### Fax

+98 21 2237 6467

#### Email

m.hajifaraji@nnftri.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences, International Branch

#### Full name of responsible person

Saeed Osati

#### Position

PhD Candidate

#### Other areas of specialty/work

#### Street address

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

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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*