

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of vitamin D supplementation on metabolic factors and obesity indices among omentin gene polymorphism genotypes in women with prediabetes

#### Protocol summary

##### Study aim

The effects of vitamin D supplementation on metabolic factors and obesity indices among omentin gene polymorphism genotypes in women with prediabetes

##### Design

A randomized, parallel-group, double-blind, placebo-controlled trial on 48 prediabetic patients in each genotype group. The software-generated random was used for randomisation.

##### Settings and conduct

The patients will be selected from the endocrinology clinic of Imam Reza Hospital in Tabriz and the healthcare centers of Tabriz. Individuals were randomly allocated into vitamin D or placebo groups. The duration of the trial will be 12 weeks. The blinding will be double-blind and the participants and researcher will remain unaware until the end of the study.

##### Participants/Inclusion and exclusion criteria

A total of 48 patients with prediabetes will be selected based on the inclusion criteria and informed written consent will be obtained from all participants before enrollment. Inclusion criteria: willingness to participate in the study, women aged 18 to 65 years with prediabetes and BMI: 18-40 Kg/m<sup>2</sup>; Exclusion criteria: Serum vitamin D level higher than 100 micrograms per liter; Smoking and alcohol; Pregnancy and lactation; Diabetes and infectious heart disease; Renal failure; Cushing's syndrome; Liver disease; Use of drugs that affect the level of fasting blood sugar

##### Intervention groups

1. Vitamin D supplement group (50000 units once every two weeks) 2. Placebo group

##### Main outcome variables

glycemic indices; serum level of lipid profile; serum omentin; anthropometric measurements; vitamin D serum

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100408003664N26**

Registration date: **2023-12-19, 1402/09/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-19, 1402/09/28**

Update count: **0**

##### Registration date

2023-12-19, 1402/09/28

##### Registrant information

##### Name

Maryam Rafrat

##### Name of organization / entity

Tabriz University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

##### Email address

rafratm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-06, 1402/09/15

##### Expected recruitment end date

2024-03-19, 1402/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effects of vitamin D supplementation on metabolic factors and obesity indices among omentin gene polymorphism genotypes in women with prediabetes

### Public title

The effects of vitamin D supplementation on metabolic factors and obesity indices among omentin gene polymorphism genotypes in women with prediabetes

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Willingness to cooperate Women aged 18 to 65 years with prediabetes Body mass index in the range of 30-40 Kg/m<sup>2</sup>

#### Exclusion criteria:

Serum Vitamin D Levels higher than 100 µg / L Smoking and alcohol Pregnancy and lactation Intake of various drugs, including drugs affecting blood sugar and lipid levels Intake of drugs or dietary supplements affecting the body weight Surgery in last three months Having chronic neurological diseases, diabetes, cardiovascular, liver, kidney, Cushing's syndrome, rheumatoid arthritis, cancer and other diseases

### Age

From **18 years** old to **65 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **48**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The eligible participants will be randomly allocated to intervention and placebo groups using software-generated random permuted blocks size of 4. The generated random sequence will be kept in a protected location and administered by an independent third party blind to the trial throughout the study. To hide, a random sequence will not be provided to the executor and will be performed sequentially for each block.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The placebo and supplement will be packed in the same number in similar packages. The method of blindness will be that the supplements and placebo will be delivered to the participants by someone other than the researcher, and the researcher will remain unaware until the end of the study.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Science

##### Street address

Tabriz University of Medical Science, Attar Neishabouri Avenue, Golgasht street, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138663134

#### Approval date

2023-11-23, 1402/09/02

#### Ethics committee reference number

IR.TBZMED.REC.1402.618

## Health conditions studied

### 1

#### Description of health condition studied

Prediabetes

#### ICD-10 code

R73.0

#### ICD-10 code description

Abnormal glucose tolerance test

## Primary outcomes

### 1

#### Description

Glycemic indices

#### Timepoint

Baseline and 12 weeks after the intervention

#### Method of measurement

Glycemic indexes (from indicators of metabolic status) including fasting blood sugar by enzymatic method, insulin by ELISA and insulin resistance by formula, will be measured or calculated.

### 2

#### Description

lipid profile

#### Timepoint

Baseline and 12 weeks after the intervention

#### Method of measurement

Lipid profile ( from indicators of metabolic status)

including total cholesterol, triglycerides and high-density lipoprotein will be measured enzymatically, and low-density lipoprotein will be calculated using the friedwald formula.

### 3

#### **Description**

Omentin

#### **Timepoint**

Baseline and 12 weeks after the intervention

#### **Method of measurement**

ELISA

### 4

#### **Description**

Serum Vitamin D

#### **Timepoint**

Baseline and 12 weeks after the intervention

#### **Method of measurement**

ELISA

## **Secondary outcomes**

### 1

#### **Description**

Obesity indices

#### **Timepoint**

Baseline and 12 weeks after the intervention

#### **Method of measurement**

Obesity indices including weight with scales and waist circumference and hip circumference will be measured with a tape measure. Body mass index will be calculated with the formula.

### 2

#### **Description**

Body composition

#### **Timepoint**

Baseline and 12 weeks after the intervention

#### **Method of measurement**

Body composition will be measured by Bio impedance (BIA) method using Tanita body composition analyzer.

### 3

#### **Description**

Dietary intake

#### **Timepoint**

Baseline and 12 weeks after the intervention

#### **Method of measurement**

The food record questionnaire will be used to assess food intake including energy, carbohydrate, protein and fat.

## **Intervention groups**

### 1

#### **Description**

Intervention group: 50000 units once every two weeks vitamin D of Zahravi company for 3 month

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Intake a Placebo perl containing sunflower oil, which is similar to vitamin D supplement in terms of dosage, color and size, once every two weeks for 12 weeks

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Endocrinology clinic of Imam Reza Hospital , Tabriz

##### **Full name of responsible person**

Roghayeh Molani-Gol

##### **Street address**

Imam Reza Hospital, Golghast Street, Tabriz

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

6717839391

##### **Phone**

+98 914 450 1684

##### **Email**

molanigol@tbzmed.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr.Aliреза Ostadrahimi

##### **Street address**

Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, Attar Neyshabori avenue, Golgasht street, Tabriz

##### **City**

Tabriz

##### **Province**

East Azarbaijan

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5166614711

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##### **Email**

nut-rc@tbzmed.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Roghayeh Molani-Gol

**Position**

PhD Student of Nutrition Sciences

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Nutrition and Food Sciences, Tabriz  
University of Medical Sciences, Attar Neyshabori  
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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Maryam Rafrat

**Position**

Ph.D in Nutrition Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Roghayeh Molani-Gol

**Position**

PhD Student of Nutrition

**Latest degree**

Master

**Other areas of specialty/work**

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**Email**

molanigol@tbzmed.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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