Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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/m2; 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 Rafraf

Name of organization / entity
Tabriz University Of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 1335 7580

Email address
rafrafm@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/m2
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 usingTanita 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.Alireza 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
Postal code
5166614711
Phone
+98 41 3336 3430
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 Avenue , Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5178741516
Phone
+98 41 3440 0334
Email
molanigol@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Maryam Rafraf
Position
Ph.D in Nutrition Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, Attar Neyshabori Avenue , Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3440 0334
Email
rafrafm@tbzmed.ac.ir

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
Nutrition
Street address
Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, Attar Neyshabori Street, Golgasht Ave, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5178741516
Phone
+98 41 3440 0334
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