

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### The effect of vitamin D supplementation on anxiety, inflammation, Omentin and Vaspin biomarkers in diabetic women

#### Protocol summary

##### Study aim

Determine the effect of vitamin D supplementation on anxiety, inflammation, Omentin and Vaspin biomarkers in diabetic women

##### Design

After selecting 50 diabetic women according to inclusion and exclusion criteria, they randomly divide to intervention and placebo groups using age blocks, Each participant will be given a code At the beginning and the end of the study, the anxiety score, the levels of omentin and vaspin adipokines, CRP, and IL-10 are compared.

##### Settings and conduct

The target population of women with diabetes are referred to Shahr-e-kord Diabetes Association. Randomized, double-blind study conducted over 16 weeks. Patient codes are not provided to the patient and the researcher. The similarity of a soft capsule of vitamin D and placebo(Both supplements were produced by Tabriz Zahravi Company) will not endanger blinding.

##### Participants/Inclusion and exclusion criteria

All participants are women and have diabetes and anxiety and the serum level of 25 hydroxy vitamin D is between 10 and 30 ng per deciliter : Those have severe psychiatric disorders or chronic disease and consume drug for depression, vitamin D or multivitamin supplement and alcohol during the last 4 month and consumption not be enter in this study.

##### Intervention groups

The intervention group every two weeks receives a soft capsule of 50,000 international units of vitamin D (produced from Zahravi, Tabriz, Iran) for 16 weeks. The control group take placebo (oral paraffin (obtained from Zahravi, Tabriz, Iran) for 16 weeks in parallel to intervention group.

##### Main outcome variables

Anxiety, stress, depression, omentin and vaspin adipokines, interleukin-10 and CRP

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170927036451N1**

Registration date: **2017-12-15, 1396/09/24**

Registration timing: **retrospective**

Last update: **2017-12-15, 1396/09/24**

Update count: **0**

##### Registration date

2017-12-15, 1396/09/24

##### Registrant information

##### Name

Siavash Fazelian

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36688487

##### Email address

siavash.fazelian@nutr.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Isfahan University of Medical Sciences

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-10-02, 1396/07/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of vitamin D supplementation on anxiety, inflammation, Omentin and Vaspin biomarkers in diabetic women

### Public title

Effect of vitamin D supplementation on anxiety and inflammation in diabetic women.

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Tendency to cooperate with research project Fasting blood higher than 126 milligram per deciliter or a two-hour blood sugar higher than 200 milligram per deciliter Age: 20 to 50 years; serum 25 Hydroxy vitamin D level less than 30 nanogram per milliliter Detection of mild or severe anxiety by the DASS21 questionnaire

#### Exclusion criteria:

Have not past medical history of attack or stroke; Severe depression in the previous years Taking Orlistat drugs (Venostat, Zenical) and anti-epileptic drugs such as phenobarbital and phenytoin Taking any supplements such as multivitamin and vitamin d during the 4 months prior to the study Smoking , alcohol intake pregnancy or lactation Not wanting to continued cooperation

### Age

From **35 years** old to **60 years** old

### Gender

Female

### Phase

2-3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

Randomized

### Randomization description

After screening, all eligible diabetic patients are randomly allocated in a 1:1 ratio to vitamin D treatment or to matching placebo by permuted block randomization method according to age block.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

After explaining the purpose of the study, all participants and investigators including the laboratory staff and Statistical analyzer are blinded to random allocation. Participants in vitamin D group receive vitamin D 50000 IU supplement while control group take placebo with the same size and color as vitamin D soft gels (Oral paraffin) which both supplements are produced by Zahrawi Tabriz Company in Iran.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezarjerib st., Isfahan,Iran.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2016-12-21, 1395/10/01

#### Ethics committee reference number

ir.mui.rec.1395.3.736

## Health conditions studied

### 1

#### Description of health condition studied

type 2 diabetes mellitus

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

vaspin hormone serum levels

#### Timepoint

Before and 16 weeks after the start of intervention

#### Method of measurement

Blood testing (by ELISA kit)

### 2

#### Description

omentin hormone serum levels

#### Timepoint

Before and 16 weeks after the start of intervention

#### Method of measurement

Blood testing (by ELISA kit)

### 3

**Description**

interleukin-10 serum levels

**Timepoint**

Before and 16 weeks after the start of intervention

**Method of measurement**

Blood testing (by ELISA kit)

### 4

**Description**

CRP serum levels

**Timepoint**

Before and 16 weeks after the start of intervention

**Method of measurement**

Blood testing (by ELISA kit)

### 5

**Description**

Anxiety score

**Timepoint**

Before and 16 weeks after the start of intervention

**Method of measurement**

by DASS21 questionnaire

### 6

**Description**

Depression score

**Timepoint**

Before and 16 weeks after the start of intervention

**Method of measurement**

by DASS21 questionnaire

### 7

**Description**

Stress score

**Timepoint**

Before and 16 weeks after the start of intervention

**Method of measurement**

by DASS21 questionnaire

## Secondary outcomes

### 1

**Description**

BMI

**Timepoint**

Before and 16 weeks after the start of intervention

**Method of measurement**

computing

### 2

**Description**

Waist circumference

**Timepoint**

Before and 16 weeks after the start of intervention

**Method of measurement**

Strip meter

### 3

**Description**

weight

**Timepoint**

Before and 16 weeks after the start of intervention

**Method of measurement**

Scales

### 4

**Description**

vitamin D serum levels

**Timepoint**

Before and 16 weeks after the start of intervention

**Method of measurement**

Blood testing (by ELISA kit)

## Intervention groups

### 1

**Description**

The intervention group every two weeks receives a soft Vitamin D Placebo Capsule (Oral Paraffin, Tabriz Zahrawi Company) for 16 weeks.

**Category**

Other

### 2

**Description**

The control group consumes a placebo capsule of vitamin D (oral paraffin, Zahravi, Tabriz) every two weeks for 16 weeks .

**Category**

Treatment - Other

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Chahar Mahal and Bakhtiari Diabetes Association

**Full name of responsible person**

Saiavash Fazelian

**Street address**

Nur Construction , North Twelve Muharram Ave.,  
Shahr-e-kord Town

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research,Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Alavi

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Vice chancellor for research,Isfahan University of Medical Sciences, Hezar jarib st, Isfahan. Iran

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+98 31 3668 8487

**Email**

pr\_nutr@mui.ac.ir

**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,Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Siavash Fazelian

**Position**

PhD candidate of Nutrition science

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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**Full name of responsible person**

Dr Reza Amani

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Professor

**Latest degree**

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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**Web page address****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