

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

City

Shahr-e-kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813769671

Phone

+98 38 3336 7012

Email

siavashfazelian@yahoo.com

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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Phone

+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

Street address

Faculty of Nutrition and Food Sciences ,Isfahan University of Medical Sciences, Hezar jarib st, Isfahan. Iran

City

Isfahan

Province

Isfahan

Postal code

8813769671

Phone

+98 383367012

Fax**Email**

siavash.fazelian@nutr.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr Reza Amani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work**Street address**

Faculty of Nutrition and Food Sciences ,Isfahan University of Medical Sciences, Hezar jarib st, Isfahan. Iran

City

Isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Phone

+98 31 3792 3175

Fax**Email**

r_amani@mail.mui.ac.ir

Web page address

Person responsible for updating data

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

Street address

Faculty of Nutrition and Food Sciences ,Isfahan University of Medical Sciences, Hezar jarib st, Isfahan. Iran

City

Isfahan

Province

Isfahan

Postal code

8813769671

Phone

+98 313367012

Fax**Email**

siavash.fazelian@nutr.mui.ac.ir

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