

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparative study on the effectiveness of omega-3, vitamin D and co-supplementation on glycemic status, serum lipids and psychological distress in reproductive-aged women with pre- diabetes and hypovitaminosis D

Protocol summary

Study aim

Determination and comparison of the effect of omega-3, vitamin D and co-supplementation on glycemic status, serum lipids and psychological distress in reproductive-aged women with pre - diabetes and hypovitaminosis D

Design

A factorial Clinical trial with control group , triple-blinded and randomized phase 3 of the trial

Settings and conduct

This study will be conducted at Shahid Rastravesh Health Center Laboratory in Karaj. 15-50 years old women with with pre - diabetes and hypovitaminosis D if they have inclusion criteria, are randomized into 4 groups according to the Stratified Block Randomization. At baseline and after 8 weeks intervention , physical activity, DASS-21 and PSQI and a 3-day food record will be collected for each subject. Also blood pressure, weight, height and waist circumference will be measured. At the beginning and at the end, a blood sample is used for estimating serum glucose indices , lipids and vitamin D. Finally, in 168 samples according to the appropriate statistical tests, the results of the comparison of efficacy of two these supplements are investigated.

Participants/Inclusion and exclusion criteria

Women aged 15-50; FBS: 100-125 mg/ml; Vitamin D < 32 ng/mL; BMI < 30 ; Not intake of drugs that interfere with vitamin D or omega-3; Not Pregnancy; Not lactation; Absence of diagnosed systemic diseases

Intervention groups

The first group (omega-3 and vitamin D placebo), the second group (Omega-3 placebo and vitamin D supplement), the third group (omega-3 supplement and vitamin D placebo), and the fourth group (supplement of omega-3 and vitamin D)

Main outcome variables

glycemic status (FBS, insulin, HOMA- IR, HOMA- B), lipid profile (triglyceride, total cholesterol, HDL cholesterol, LDL-cholesterol) and psychological distress (depression, anxiety, stress and quality of sleep)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100130003226N17**

Registration date: **2019-02-09, 1397/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-09, 1397/11/20**

Update count: **0**

Registration date

2019-02-09, 1397/11/20

Registrant information

Name

Mahrokh Dolatian

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

m_dolatian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study on the effectiveness of omega-3, vitamin D and co-supplementation on glycemic status, serum lipids and psychological distress in reproductive-aged women with pre- diabetes and hypovitaminosis D

Public title

Effect of omega-3 and vitamin D on women with pre-diabetes and hypo vitaminosis D

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Reproductive-aged women (age15-50 years) FBS 100-125 mg/ml □ serum vitamin D level < 32 ng/mL BMI < 30

Exclusion criteria:

Diagnosed pathological conditions such as thyroid or para thyroid disorders, PCO, seizures, liver or kidney disease, neurological disorders, cancer, cardiovascular disease, type 1 or 2 diabetes, Sarcoidosis or other Granulomatous disorder Intakes vitamin D or omega-3 during the last 6 months Breast feeding, pregnant, and/or planning for pregnancy in the following 2 months Intake of drugs that interact with omega-3 [including aspirin or anticoagulants (warfarin, heparin)] or with vitamin D (such as cardiac glycosides, Cholestyramine, anticonvulsant drugs or thiazides) Taking herbal or chemical drugs that affect serum lipids or blood glucose level In case of taking prescribed supplements different from study protocol Unwillingness to provide blood sample during the initial or final visits or not to continue participating in research

AgeFrom **15 years** old to **50 years** old**Gender**

Female

Phase

3

Groups that have been masked

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

Sample sizeTarget sample size: **168****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization method:Eligible participants are randomized into treatments with either double placebo,

vitamin D alone, omega-3 alone or double active (vitamin D and omega-3) groups according to the Stratified Block Randomization. Random unit: Block randomization is done in equal block sizes of 4 to ensure the balance between groups. Stratified randomization will be used to control serum vitamin D level (Vitamin D<20 ng/ml, Vitamin D: 20~32 ng/ml) distribution. Randomization Tool: Statistical software Randomization is carried out by an individual who is not involved in trial data collection and analysis. Allocation concealment:The intervention allocation will be blinded to the study investigators, participants and statistical analyzer.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Vitamin D and omega-3 supplements and placebos were produced by Zahravi Pharmaceutical Company (Tabriz, Iran).The appearance of the placebo capsule was indistinguishable in color, shape, size, packaging, smell and taste from vitamin D and omega-3 capsules. Packaging and Labeling of drugs for each group is done by an individual who is not involved in trial data collection and analysis The type of supplements in each group is blinded as A, B, C and D packages for investigators, participants and statistical analyzer.

Placebo

Used

Assignment

Factorial

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

6th Floor, Bldg No.2 SBUMS,Parvaneh Str., Yemeni Ave, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-11-04, 1397/08/13

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.615

Health conditions studied**1****Description of health condition studied**

prediabetes

ICD-10 code

R73.0

ICD-10 code description

Abnormal glucose tolerance test

2

Description of health condition studied

Vitamin D deficiency

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

Primary outcomes

1

Description

glycemic status[fasting blood sugar and insulin, homeostasis model assessment-insulin resistance (HOMA-IR), homeostasis model assessment-beta cell function (HOMA-B)]

Timepoint

at beginning and after 8 weeks intervention

Method of measurement

Blood sampling and calculating (HOMA-IR) and (HOMA-B)

2

Description

serum lipids (triglyceride, low-density lipoprotein-cholesterol, high-density lipoprotein-cholesterol, total cholesterol)

Timepoint

at beginning and after 8 weeks intervention

Method of measurement

Blood sampling

3

Description

scores of Depression Anxiety Stress Scale (DASS 21)

Timepoint

at beginning and after 8 weeks intervention

Method of measurement

Depression Anxiety Stress Scale (DASS 21)

4

Description

Score of Pittsburgh Sleep Quality Index (PSQI)

Timepoint

at beginning and after 8 weeks intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

1

Description

weight

Timepoint

At beginning and after 8 weeks intervention

Method of measurement

Digital scale

2

Description

Body mass index (BMI)

Timepoint

At beginning and after 8 weeks intervention

Method of measurement

It will be calculated using the height and weight measurements w/h² (w: weight in kg and h: height in meters).

3

Description

Systolic and diastolic blood pressure

Timepoint

At beginning and after 8 weeks intervention

Method of measurement

Digital manometer

4

Description

Waist circumference

Timepoint

At beginning and after 8 weeks intervention

Method of measurement

Nonelastic tape

Intervention groups

1

Description

Intervention group1: 1000 mg omega-3 [each capsule containing 180 mg eicosapentaenoic acid (EPA) and 120 mg docosahexaenoic acid (DHA)] twice a day + vitamin D placebo every 2 weeks for 8 weeks. Omega3 supplement is produced by Zahravi Pharmaceutical Company (IRC: 1228058530 / GTIN: 06260155920675). Vitamin D placebo is produced by Zahravi Pharmaceutical Company

Category

Prevention

2

Description

Intervention group2: Capsule vitamin D (50,000 IU) every 2 weeks + omega-3 placebo twice a day for 8 weeks. Vitamin D supplement is produced by Zahravi Pharmaceutical Company (IRC: 1228055799/ GTIN: 06260155960213). Omega3 placebo is produced by Zahravi Pharmaceutical Company

Category

Prevention

3**Description**

Intervention group3: 1000 mg omega-3 [each capsule containing 180 mg eicosapentaenoic acid (EPA) and 120 mg docosahexaenoic acid (DHA)] twice a day + Capsule vitamin D (50,000 IU) every 2 weeks.Omega3 supplement is produced by Zahravi Pharmaceutical Company (IRC: 1228058530 / GTIN: 06260155920675).Vitamin D supplement is produced by Zahravi Pharmaceutical Company (IRC: 1228055799/ GTIN: 06260155960213).

Category

Prevention

4**Description**

Control group:4 Vitamin D placebo+ omega-3 placebo for 8 weeks.Omega3 and Vitamin D placebo is produced by Zahravi Pharmaceutical Company

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

آزمایشگاه مرکز بهداشت شهید راست روش

Full name of responsible person

معصومه رجیبی نائینی

Street address

Vahdat st.South Taleghani blvd

City

Karaj

Province

Alborz

Postal code

3133968111

Phone

+98 26 3270 0011

Fax

+98 26 3270 0011

Email

alborzuniverlab@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

University Building No. 2 of ShahidBeheshti University

of Medical Sciences, Parvaneh Str., Yemeni Ave,
Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Fax

+98 21 2243 9981

Email

zarghi@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahrokh Dolatian

PositionVice-Chancellor of Research, Faculty of Nursing and
Midwifery**Latest degree**

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Valiasr Str., intersection of Niyayesh

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 218865536671

Fax

+98 21 8820 2521

Email

m_dolatian@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dolatian Mahrokh

Position

Vice-Chancellor of Research, Faculty of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Valiasr Str., intersection of Niyayesh

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 218865536671

Fax

+98 21 8820 2512

Email

m_dolatian@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoumeh Rajabi Naeeni

Position

PhD student reproductive health

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway. School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1996835119

Phone

+98 21 8820 2512

Fax

+98 21 8820 2512

Email

rajabishirin@gmail.com

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