Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Comparative study on the effectiveness of omega-3, vitamin D and co-supplementation on glycemic status, serum lipids and psycological 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 psycological distress in reproductive-aged women with pre - diabetes and hypovitminosis 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 hypovitminosis D if they have inclution 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, in168 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 oromega-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 Scenices

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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 psycological 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
Age
From **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 size
Target 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 placeboes 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
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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. 0mega3 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). 0mega3 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.0mega3 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.0mega3 and Vitamin D placebo is produced by Zahravi Pharmaceutical Company
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
Position
Vice-Chancellor of Research, Faculty of Nursing and Midwifery
Latest degree
Ph.D.
Other areas of specialty/work
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Latest degree
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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