

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

The effects of omega-3 supplementation on inflammatory factors, oxidative stress biomarkers, pregnancy outcomes, and gene expression related to insulin, lipid, and inflammation in women with gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of omega-3 supplementation on inflammatory factors, oxidative stress biomarkers, pregnancy outcomes, and gene expression related to insulin, lipid, and inflammation in patients with gestational diabetes mellitus.

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive omega-3 supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with gestational diabetes referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with gestational diabetes mellitus aged 18 to 40 years. Exclusion criteria: Kidney or liver diseases, needing insulin therapy, pre-eclampsia, eclampsia, hypo and hyperthyroidism, smokers

Intervention groups

Intervention group: 2000 mg omega-3 daily (Barij Essence, Kashan, Iran) for 6 weeks orally. Control group: Placebo capsule (Barij Essence, Kashan, Iran), for 6 weeks orally.

Main outcome variables

Outcomes: Gene expression related to PPAR- γ (primary outcome) and pregnancy outcomes, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation and lipid (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N42**

Registration date: **2018-12-19, 1397/09/28**

Registration timing: **retrospective**

Last update: **2019-09-21, 1398/06/30**

Update count: **1**

Registration date

2018-12-19, 1397/09/28

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-03, 1397/04/12

Expected recruitment end date

2018-08-03, 1397/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of omega-3 supplementation on inflammatory factors, oxidative stress biomarkers, pregnancy outcomes, and gene expression related to insulin, lipid, and inflammation in women with gestational diabetes

Public title

The effects of omega-3 supplementation in gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Patients with gestational diabetes mellitus. Individuals aged 18 to 40 years.

Exclusion criteria:

Exclusion criteria: Kidney or liver diseases Needing insulin therapy Pre-eclampsia Eclampsia Hypo and hyperthyroidism Smokers

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and \geq 25 kg/m²) and age (<30 and \geq 30 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Kosar clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

1771844351

Approval date

2018-07-02, 1397/04/11

Ethics committee reference number

IR.ARAKMU.REC.1397.114

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Gestational diabetes mellitus

Primary outcomes

1

Description

Expressed levels of PPAR- γ gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

Secondary outcomes

1

Description

Hs-CRP

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Elisa kit

2

Description

Nitric oxide

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Glutathione

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

5

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Expressed levels of LDLR gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

7

Description

Expressed levels of VEGF gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

8

Description

Expressed levels of TGF- β gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

9

Description

Expressed levels of TNF gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

10

Description

Expressed levels of IL-1 gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

11

Description

Insulin

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Elisa kit

12

Description

Insulin resistance

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Calculation using HOMA formula

13

Description

Total cholesterol

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

14

Description

Triglycerides

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

15

Description

HDL

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

16

Description

LDL

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

17

Description

FPG

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

18

Description

VLDL

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: 2000 mg omega-3 daily (Barij Essence, Kashan, Iran) for 6 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (Barij Essence, Kashan, Iran), for 6 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Clinic

Full name of responsible person

Mehri Jamilian

Street address

Emam Khomeyni Avenue, Arak

City

Arak

Province

Markazi

Postal code

1771844351

Phone

+98 31 5546 3378

Email

jamilian.m@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammad Arjmandzadegan

Street address

Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

1771844351

Phone

+98 31 5546 3378

Email

Arjmandzadegan.m@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

1771844351

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address

asemi_z@kaums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

1771844351

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

1771844351

Phone

+98 31 5546 3378

Fax**Email**

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