Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 facors, 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 ≥25 kg/m2) and age (<30 and ≥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
Isfehan
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
Isfehan
Postal code
1771844351
Phone
+98 31 5546 3378
Fax
Email
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
Isfehan
Postal code
1771844351
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.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