Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of fish oil supplementation compared with the placebo on levels of gene expression related with glycemic control and inflammatory factors in women with gestational diabetes

Protocol summary

Study aim
Objective: The aim of this study is to determine the effects of fish oil supplementation on levels of gene expression related with glycemic control and inflammatory factors in patients with gestational diabetes.

Design
Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct
Population and sample size: 40 patients with gestational diabetes of eligible and referred to Kosar gynecology Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with gestational diabetes and aged 18 to 40 years will be included in this study. Exclusion criteria:Taking fish oil supplements, insulin therapy, placenta abruption, pre-eclampsia, eclampsia, hypo and hyperthyroidism, smokers.

Intervention groups
Intervention group: 1000 mg fish oil (Barij Essence, Kashan, Iran), twice a day, for 6 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), twice a day, for 6 weeks orally.

Main outcome variables
Outcomes: Levels of gene expression related with glycemic control (primary outcomes) and inflammatory factors will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201610015623N90**
Registration date: **2016-10-11, 1395/07/20**
Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**
Update count: **1**

Registration date
2016-10-11, 1395/07/20

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 36 1534 3570

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Recruitment status
Recruitment complete

Funding source
Arak University of Medical Sciences

Expected recruitment start date
2016-07-26, 1395/05/05

Expected recruitment end date
2016-08-10, 1395/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Clinical trial of the effect of fish oil supplementation compared with the placebo on levels of gene expression related with glycemic control and inflammatory factors in women with gestational diabetes

Public title
Effect of supplementation in treatment of women with gestational diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with gestational diabetes Aged 18 to 40 years
Exclusion criteria:
Taking fish oil supplements Insulin therapy Placenta abruption Pre-eclampsia Eclampsia Hypo and hyperthyroidism Smokers
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.
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
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2016-07-25, 1395/05/04
Ethics committee reference number
IR.ARAKMU.REC.1395.160

Health conditions studied

1

Description of health condition studied
Gestational diabetes
ICD-10 code
O24.9
ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
PPAR-γ
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
PCR

Secondary outcomes

1

Description
Gene expression of interleukin 1
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
PCR

2

Description
Gene expression of tumor necrosis factor alpha
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
PCR

3

Description
Gene expression of interleukin 8
Timepoint
At the beginning of the study and after 6 weeks of intervention

Method of measurement
PCR

4

Description
Gene expression of LDLR
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
PCR

5

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Insulin
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
ELISA kit

7

Description
Insulin resistance
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Calculation using HOMA formula

8

Description
Triglycerides
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
Total cholesterol
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
HDL
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

11

Description
High-sensitivity C-reactive protein
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
ELISA kit

12

Description
Newborn's head circumference
Timepoint
Delivery time
Method of measurement
Tape

13

Description
Polyhydramnios
Timepoint
End-of-trial
Method of measurement
Sonographic

14

Description
Apgar score
Timepoint
Delivery time
Method of measurement
Clinical observation

15

Description
Preterm delivery
Timepoint
After delivery
Method of measurement
Medical record

16

Description
Maternal pre-eclampsia
Timepoint
After delivery
Method of measurement
Medical record

17

Description
Newborn's length
Timepoint
Delivery time
Method of measurement
Delivery time

18

Description
Newborn's weight
Timepoint
Delivery time
Method of measurement
Scale

Intervention groups

1

Description
Intervention group: 1000 mg fish oil (Barij Essence, Kashan, Iran), twice a day, for 6 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), twice a day, for 6 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar gynecology clinic
Full name of responsible person
Mehri Jamilian
Street address
Emam Khomeyni Avenue, Arak
City
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Province
Markazi
Postal code
3848176941
Phone
+98 86 3223 3823
Email
jamilian.mehri@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Mohammad Rafiee
Street address
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
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Postal code
3848176941
Phone
+98 86 3417 3639
Email
research@arakmu.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, 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
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
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Person responsible for scientific inquiries

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Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Kashan University of Medical Sciences

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Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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