

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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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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

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Emam Khomeyni Avenue, Arak

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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

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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

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position