

# 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)

###### Phone

+98 36 1534 3570

###### Email address

asemi\_z@kaums.ac.ir

##### 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- $\gamma$

**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

Arak

##### 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

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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

##### Street address

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##### Province

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## 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**

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**Latest degree**

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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**