

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of omega-3 supplementation on inflammatory factors, biomarkers of oxidative stress and pregnancy outcomes in gestational diabetes

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of omega-3 supplementation on inflammatory factors, biomarkers of oxidative stress and pregnancy outcomes in gestational diabetes.

##### Design

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

##### Settings and conduct

Population and sample size: Among patients with gestational diabetes referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 54 patients will be selected according to inclusion and exclusion criteria.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation.

Exclusion Criteria: Pre-existing diabetes, required complex diets, chronic medical conditions, significant psychiatric disease, smokers, kidney or liver diseases, chronic hypertension, hypothyroidism.

##### Intervention groups

Intervention group: Omega-3 pearl, 1000 mg, daily, for 6 weeks orally. Control group: Placebo pearl, daily, for 6 weeks orally.

##### Main outcome variables

Outcomes: Pregnancy outcomes (primary outcomes), hs-CRP, total nitrite and biomarkers of oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201406305623N20**  
Registration date: **2014-07-16, 1393/04/25**  
Registration timing: **retrospective**

Last update: **2019-10-25, 1398/08/03**

Update count: **1**

##### Registration date

2014-07-16, 1393/04/25

##### 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 Science

##### Expected recruitment start date

2014-05-10, 1393/02/20

##### Expected recruitment end date

2014-05-28, 1393/03/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of omega-3 supplementation on inflammatory

factors, biomarkers of oxidative stress and pregnancy outcomes in gestational diabetes

**Public title**

Effect of supplementation in treatment of gestational diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation

**Exclusion criteria:**

Pre-existing diabetes  
Required complex diets  
Chronic medical conditions  
Significant psychiatric disease  
Smokers  
Kidney or liver diseases  
Chronic hypertension  
Hypothyroidism

**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: **54**

**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**

Arak University of Medical Sciences

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Vice-chancellor for Education and Research, Sardasht Avenue, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814113634

**Approval date**

2014-05-09, 1393/02/19

**Ethics committee reference number**

93-165-20

**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**

Infants' weight

**Timepoint**

Delivery time

**Method of measurement**

Scale

**2****Description**

Infants' head circumference

**Timepoint**

Delivery time

**Method of measurement**

Tape

**3****Description**

Newborns' length

**Timepoint**

Delivery time

**Method of measurement**

Tape

**4****Description**

Polyhydramnios

**Timepoint**

After the intervention

**Method of measurement**

Sonography

**5****Description**

Newborn's bilirubin

### **Timepoint**

Delivery time

### **Method of measurement**

Enzymatic kit

### **6**

#### **Description**

Apgar score

#### **Timepoint**

Delivery time

#### **Method of measurement**

Clinical observation

### **7**

#### **Description**

Preterm delivery

#### **Timepoint**

After delivery

#### **Method of measurement**

Medical record

### **8**

#### **Description**

Maternal pre-eclampsia

#### **Timepoint**

After delivery

#### **Method of measurement**

Medical record

### **9**

#### **Description**

Maternal hospitalization

#### **Timepoint**

After delivery

#### **Method of measurement**

Medical record

## **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**

Total antioxidant

#### **Timepoint**

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

#### **Method of measurement**

Spectrophotometry

### **4**

#### **Description**

Malondialdehyde

#### **Timepoint**

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

#### **Method of measurement**

Spectrophotometry

### **5**

#### **Description**

Glutathione

#### **Timepoint**

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

#### **Method of measurement**

Spectrophotometry

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Omega-3 pearl, 1000 mg, daily, for 6 weeks orally.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Placebo pearl, daily, for 6 weeks orally.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Kossar Clinic

##### **Full name of responsible person**

Mehri Jamilian

##### **Street address**

Emam Khomeyni Avenue, Arak

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jamilian.mehri@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mohammad Rafiee

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**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**

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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## Person responsible for updating data

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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