

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Clinical trial of the effect of combined omega-3 fatty acids and vitamin D supplementation compared with the placebo on metabolic profiles in patients with gestational diabetes

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of combined omega-3 fatty acids and vitamin D supplementation on metabolic profiles such as markers of insulin metabolism and lipid profiles in patients with gestational diabetes.

##### Design

Parallel group, double-blind (both patients and researchers) randomized controlled clinical trial.

##### Settings and conduct

Population and sample size: 140 eligible patients with GDM among pregnant women, referred to Kosar Gynecology Clinic affiliated to Arak University of Medical Sciences, Arak, Iran will be selected to participate in the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with gestational diabetes in the age range of 18 to 40 years old. Exclusion criteria: taking vitamin D and/or omega-3 fatty acids supplements, taking insulin, placenta abruption, preeclampsia, eclampsia, hypo and hyperthyroidism, smokers, kidney or liver diseases.

##### Intervention groups

Control group: Placebo (Zahravi, Tabriz, Iran), for 6 weeks orally. Intervention group 1: Combined 1000 mg omega-3 fatty acids twice a day (Zahravi, Tabriz, Iran) and 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally. Intervention group 2: 1000 mg omega-3 fatty acids (Zahravi, Tabriz, Iran), twice a day, for 6 weeks orally. Intervention group 3: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally.

##### Main outcome variables

Markers of insulin metabolism (primary outcomes); lipid profiles

#### 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: **IRCT201605135623N78**  
Registration date: **2016-05-21, 1395/03/01**  
Registration timing: **retrospective**

Last update: **2019-11-08, 1398/08/17**

Update count: **1**

##### Registration date

2016-05-21, 1395/03/01

##### 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

Vice chancellor for research, Arak University of Medical Sciences

##### Expected recruitment start date

2016-03-06, 1394/12/16

**Expected recruitment end date**

2016-05-05, 1395/02/16

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical trial of the effect of combined omega-3 fatty acids and vitamin D supplementation compared with the placebo on metabolic profiles in patients with gestational diabetes

**Public title**

Effect of supplementation in treatment of patients with gestational diabetes

**Purpose**

Treatment

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

Patients with gestational diabetes in the age range of 18 to 40 years

**Exclusion criteria:**

Taking vitamin D and/or omega-3 fatty acids supplements  
Taking insulin  
Placenta abruption  
Preeclampsia  
Eclampsia  
Hypo and hyperthyroidism  
Smokers  
Kidney or liver diseases

**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: **140**

**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**

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Clinic who is not involved in the trial and not aware of random sequences will allocate the numbered bottles of capsules to participants. Supplements and placebo are in the same packaging at the pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

**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**

Isfahan

**Postal code**

3814113634

**Approval date**

2016-03-05, 1394/12/15

**Ethics committee reference number**

IR.ARAKMU.REC.1394.373

**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**

Insulin resistance

**Timepoint**

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

**Method of measurement**

Calculation using HOMA formula

**2****Description**

Insulin

**Timepoint**

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

**Method of measurement**

ELISA test

## Secondary outcomes

### 1

#### **Description**

Triglycerides

#### **Timepoint**

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

#### **Method of measurement**

Enzymatic kit

### 2

#### **Description**

HDL-cholesterol

#### **Timepoint**

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

#### **Method of measurement**

Enzymatic kit

### 3

#### **Description**

Total cholesterol

#### **Timepoint**

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

#### **Method of measurement**

Enzymatic kit

### 4

#### **Description**

LDL

#### **Timepoint**

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

#### **Method of measurement**

Enzymatic kit

### 5

#### **Description**

VLDL

#### **Timepoint**

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

#### **Method of measurement**

Enzymatic kit

### 6

#### **Description**

FPG

#### **Timepoint**

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

#### **Method of measurement**

Enzymatic kit

## Intervention groups

### 1

#### **Description**

Control group: Placebo (Zahravi, Tabriz, Iran), for 6 weeks orally.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 1: Combined 1000 mg omega-3 fatty acids twice a day (Zahravi, Tabriz, Iran) and 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Intervention group 2: 1000 mg omega-3 fatty acids (Zahravi, Tabriz, Iran), twice a day, for 6 weeks orally.

#### **Category**

Treatment - Drugs

### 4

#### **Description**

Intervention group 3: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally.

#### **Category**

Treatment - Drugs

## Recruitment centers

### 1

#### **Recruitment center**

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

Kosar outpatient Clinic

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

Mehri Jamilian

##### **Street address**

Emam Khomeyni Avenue, Arak

##### **City**

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##### **Phone**

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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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Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak

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**Email**

research@aums.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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**Position**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Zatollah Asemi

**Position**

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**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