

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of omega-3 supplementation on insulin resistance and lipid profiles in women with gestational diabetes

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of omega-3 supplementation on insulin resistance and lipid profiles in gestational diabetes.

##### Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers.

##### Settings and conduct

Among patients with GDM referred to Naghavi outpatient Clinic affiliated to Kashan University of Medical Sciences and Kosar outpatient Clinic affiliated to Arak University of Medical Sciences, 56 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 6 weeks after the intervention. At the beginning and the end of the intervention: 6 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion and Exclusion Criteria: Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation will be included in this study. The use of substitute treatments including hormone or vitamin supplements as well as those with pre-eclampsia, complete bed rest (CBR), intra uterine fetal death (IUFD), placenta abruption and preterm delivery will be excluded in the study.

##### Intervention groups

Intervention: Patients will be assigned to receive omega-3 supplement (n=28) and placebo (n=28).

##### Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles (secondary outcomes) will be quantified at study baseline and end-of-trial

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201312265623N16**

Registration date: **2014-03-10, 1392/12/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-11, 1398/05/20**

Update count: **1**

##### Registration date

2014-03-10, 1392/12/19

##### 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

Kashan University of Medical Sciences

##### Expected recruitment start date

2014-03-03, 1392/12/12

##### Expected recruitment end date

2014-03-15, 1392/12/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of omega-3 supplementation on insulin resistance and lipid profiles in women with gestational diabetes

## Public title

The effect of omega-3 in the 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:

The use of substitute treatments including hormone or vitamin supplements Patients with pre-eclampsia Complete bed rest (CBR) Intra uterine fetal death (IUFD) Placenta abruption Preterm delivery

## 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: **56**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients were randomly allocated into two groups to take either supplements or placebo. 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

Kashan University of Medical Sciences

##### Street address

Bolvare Ghotbe Ravandi, Kashan

##### City

Kashan

##### Province

Isfahan

##### Postal code

8115187159

##### Approval date

2014-03-03, 1392/12/12

##### Ethics committee reference number

29/5/1/5007/P

## Health conditions studied

### 1

#### Description of health condition studied

Gestational diabetes mellitus

#### ICD-10 code

O24.9

#### ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

## Primary outcomes

### 1

#### Description

Insulin

#### Timepoint

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

#### Method of measurement

Elisa kit

### 2

#### Description

Insulin resistance

#### Timepoint

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

#### Method of measurement

Calculation using HOMA formula

## Secondary outcomes

### 1

#### Description

Total cholesterol

#### Timepoint

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

#### Method of measurement

Enzymatic kit

### 2

#### Description

Triglycerides

#### Timepoint

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

**Method of measurement**

Enzymatic kit

**3**

**Description**

HDL-cholesterol

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**Intervention groups**

**1**

**Description**

Intervention group: Magnesium tablet, 250 mg, daily for 6 weeks orally.

**Category**

Treatment - Drugs

**2**

**Description**

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

**Category**

Treatment - Drugs

**3**

**Description**

Control group: Placebo tablet for magnesium, daily for 6 weeks orally.

**Category**

Placebo

**4**

**Description**

Control group: Placebo pearl for omega-3, daily for 6 weeks orally.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Naghavi Clinic

**Full name of responsible person**

Zatollah Asemi

**Street address**

Shahid Rajaei Avenue, Kashan

**City**

Kashan

**Province**

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**Postal code**

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**Phone**

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**2**

**Recruitment center**

**Name of recruitment center**

Kosar Clinic

**Full name of responsible person**

Mehri Jamilian

**Street address**

Emam Khomeyni Avenue, Arak

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**Province**

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3814113634

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jamilian.mehri@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

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Bolvare Ghotbe Ravandi, Kashan

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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**

Kashan 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**  
PhD of Nutrition  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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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