

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of combined omega-3 and vitamin E supplementation on metabolic profiles in gestational diabetes

#### Protocol summary

##### Study aim

Objective: The aim of the current study is to evaluate the effects of combined omega-3 and vitamin E supplementation on metabolic profiles in 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: 60 patients with gestational diabetes of eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

##### Participants/Inclusion and exclusion criteria

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

Exclusion criteria: Patients with premature preterm rupture of membrane, placenta abruption, pre-eclampsia, eclampsia, hypo and hyperthyroidism, urinary tract infection, smokers, kidney or liver diseases, required commencing insulin therapy during intervention

##### Intervention groups

Intervention group: Combined omega-3 and vitamin E pearl, 1000 mg omega-3 and 400 IU vitamin E, daily, for 6 weeks orally. Control group: Placebo pearl, daily, for 6 weeks orally.

##### Main outcome variables

Outcomes: Glucose homeostasis parameters (primary outcomes) and lipid profiles (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: **IRCT201506085623N43**

Registration date: **2015-06-23, 1394/04/02**

Registration timing: **retrospective**

Last update: **2019-10-19, 1398/07/27**

Update count: **1**

##### Registration date

2015-06-23, 1394/04/02

##### 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 Science

##### Expected recruitment start date

2015-05-31, 1394/03/10

##### Expected recruitment end date

2015-06-14, 1394/03/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of combined omega-3 and vitamin E supplementation on metabolic profiles 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 old diagnosed with GDM at 24-28 weeks' gestation

### Exclusion criteria:

Patients with premature preterm rupture of membrane Placenta abruption Pre-eclampsia Eclampsia Hypo and hyperthyroidism Urinary tract infection Smokers Kidney or liver diseases Required commencing insulin therapy during intervention

## 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: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

At study baseline, after balanced blocked randomisation, subjects will be allocated into two groups to take supplements (n=30) or the standard diet (n=30). 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 Science

#### Street address

Ghotbe Ravandi Boulevard, Kashan

#### City

Kashan

#### Province

Isfahan

#### Postal code

81151-87159

#### Approval date

2015-05-31, 1394/03/10

#### Ethics committee reference number

9434

## 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

Fasting plasma glucose

#### Timepoint

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

#### Method of measurement

Enzymatic

### 2

#### Description

Insulin

#### Timepoint

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

#### Method of measurement

Elisa

### 3

#### 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

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**

VLDL

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**5**

**Description**

LDL

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**Intervention groups**

**1**

**Description**

Intervention group: Combined omega-3 and vitamin E pearl, 1000 mg omega-3 and 400 IU vitamin E, daily, for 6 weeks orally.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Placebo pearl, 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

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Shahid Rajaee Avenue, Kashan

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Science

**Full name of responsible person**

Gholamali Hamidi

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research@kaums.ac.ir

**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 Science

**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

asemi\_r@yahoo.com  
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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Zatollah Asemi  
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Associate professor  
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Ph.D.  
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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