

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Clinical trial of the effect of combined vitamin D and evening primrose oil supplementation on metabolic profiles in gestational diabetes

#### Protocol summary

##### Study aim

The aim of the current study is to evaluate the effects of combined vitamin D and evening primrose oil supplementation on metabolic profiles in gestational diabetes.

##### Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

##### Settings and conduct

Population and sample size: 60 patients with GDM among pregnant women of eligible and referred to Gynecology Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: In the current study, pregnant women aged 18-40 years with gestational diabetes (GDM) at weeks 24-28 of gestation will be included. Exclusion criteria: Pre-eclampsia, eclampsia, hypo- and hyperthyroidism, urinary tract infection, smokers, kidney or liver diseases and those requiring commencement of insulin therapy during treatment.

##### Intervention groups

Intervention: Patients will be assigned to receive either combined vitamin D and evening primrose oil supplements (intervention group: n=30) or placebo (control group: n=30).

##### Main outcome variables

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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201509115623N52**

Registration date: **2015-09-16, 1394/06/25**

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

Last update: **2019-09-22, 1398/06/31**

Update count: **1**

##### Registration date

2015-09-16, 1394/06/25

##### 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 Sciences

##### Expected recruitment start date

2015-09-02, 1394/06/11

##### Expected recruitment end date

2015-09-18, 1394/06/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of the effect of combined vitamin D and evening primrose oil 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 Diagnosed with GDM at weeks 24-28 of gestation

**Exclusion criteria:**  
Pre-eclampsia Eclampsia hypo- and hyperthyroidism  
Urinary tract infection Smokers Kidney or liver diseases  
Those requiring commencement of insulin therapy during treatment.

**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**  
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 Education and Research, Sardasht Avenue, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3814113634

#### Approval date

2015-09-01, 1394/06/10

#### Ethics committee reference number

IR.ARAKMU.REC.1394.161

## 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

#### 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

Questionnaire

## Secondary outcomes

### 1

#### Description

Fasting blood sugar

#### 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

Total cholesterol

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**4**

**Description**

HDL-cholesterol

**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**

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 vitamin D and evening primrose oil pearl, 1000 IU vitamin D plus 1000 mg evening primrose oil, 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**

Gynecology Clinic

**Full name of responsible person**

Mehri Jamilian

**Street address**

Emam Khomeyni Avenue, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814113634

**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

**Street address**

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

**City**

Arak

**Province**

Markazi

**Postal code**

3814113634

**Phone**

+98 86 3223 3823

**Email**

rafiee-m@iums.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**

PhD of Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

1771844351

**Phone**

+98 31 5546 3378

**Email**

asemi\_z@kaums.ac.ir

**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**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

1771844351

**Phone**

+98 31 5546 3378

**Fax**

**Email**

asemi\_z@kaums.ac

**Web page address**

**Person responsible for updating data**

**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**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

1771844351

**Phone**

+98 31 5546 3378

**Fax**

**Email**

asemi\_z@kaums.ac

**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