

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Clinical trial of the effect of selenium supplementation compared with the placebo on gene expression related to insulin and lipid in women with gestational diabetes mellitus

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of selenium supplementation on gene expression related to insulin and lipid in patients with gestational diabetes mellitus

##### Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive selenium supplement (n=20) or placebo (n=20).

##### Settings and conduct

Among patients with gestational diabetes referred to Akbarabadi Clinic affiliated to Iran University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with gestational diabetes aged 18 to 40 years. Non inclusion criteria: Thyroid disorders, smokers, pre-eclampsia, eclampsia, those with kidney or liver diseases and required insulin therapy during intervention, taking selenium supplements or other antioxidants 3 months before the intervention .

##### Intervention groups

Intervention group: Selenium supplements (Nature, California, USA), 200 µg, daily, for 6 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily, for 6 weeks orally.

##### Main outcome variables

Outcomes: Expressed levels of PPAR-γ gene (primary outcome) and Expressed levels of GLUT-1, Lp(a) and LDL-R genes (secondary outcomes) will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170513033941N35**

Registration date: **2018-06-20, 1397/03/30**

Registration timing: **retrospective**

Last update: **2019-09-11, 1398/06/20**

Update count: **1**

##### Registration date

2018-06-20, 1397/03/30

##### Registrant information

##### Name

Mohammadreza Sharif

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5546 3378

##### Email address

ostadmohammadi-vr@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-16, 1397/02/26

##### Expected recruitment end date

2018-06-16, 1397/03/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Clinical trial of the effect of selenium supplementation compared with the placebo on gene expression related to insulin and lipid in women with gestational diabetes mellitus

## Public title

Effect of selenium supplementation in treatment of gestational diabetes mellitus

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Inclusion criteria: Patients with gestational diabetes mellitus. Individuals aged 18 to 40 years.

### Exclusion criteria:

Thyroid disorders Smokers Pre-eclampsia Eclampsia Kidney or liver diseases Requiring insulin therapy during intervention Taking selenium supplements or other antioxidants 3 months before the 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: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

At study baseline, after balanced randomisation, subjects will be allocated into two groups to receive supplement 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

Ethics committee of Iran University of Medical

Sciences

#### Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Approval date

2018-05-15, 1397/02/25

#### Ethics committee reference number

IR.IUMS.FMD.REC.1396.9411290008

## Health conditions studied

### 1

#### Description of health condition studied

Gestational diabetes mellitus

#### ICD-10 code

O24.9

#### ICD-10 code description

Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium

## Primary outcomes

### 1

#### Description

Expressed levels of PPAR- $\gamma$  gene

#### Timepoint

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

#### Method of measurement

PCR

## Secondary outcomes

### 1

#### Description

Expressed levels of GLUT-1 gene

#### Timepoint

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

#### Method of measurement

PCR

### 2

#### Description

Expressed levels of Lp(a) gene

#### Timepoint

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

#### Method of measurement

PCR

### 3

**Description**

Expressed levels of LDL-R gene

**Timepoint**

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

**Method of measurement**

PCR

## Intervention groups

### 1

**Description**

Intervention group: Selenium supplements (Nature, California, USA), 200 µg, daily, for 6 weeks orally.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Placebo (Barij Essence, Kashan, Iran), daily, for 6 weeks orally.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Akbarabadi Clinic

**Full name of responsible person**

Dr. Maryam Karamali

**Street address**

Akbarabadi Hospital, Mowlavi Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1168743514

**Phone**

+98 21 5560 6034

**Email**

karamali.maryam2@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Ali Javad Moosavi

**Street address**

Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1168743514

**Phone**

+98 21 86701

**Email**

dr\_moosavi\_@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

8715981151

**Phone**

+98 31 5546 3378

**Fax****Email**

asemi\_z@kaums.ac.ir

**Web page address**

## 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**

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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

**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