

# 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 involved in inflammation signaling pathway in patients with gestational diabetes

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of selenium supplementation on gene expression involved in inflammation signaling pathway in patients with 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: 40 patients with gestational diabetes of eligible and referred to Kosar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with gestational diabetes and aged 18 to 40 years will be included in this study.

Exclusion criteria: Taking selenium supplements before the intervention, needing insulin therapy, placenta abruption, pre-eclampsia, eclampsia, hypo and hyperthyroidism and Smokers

##### Intervention groups

Intervention: Patients will be assigned to receive either selenium (n=20) or placebo (n=20). Selenium and placebo capsules are similar in shape and size.

##### Main outcome variables

Outcomes: Gene expression involved in TNF- $\alpha$  (primary outcomes), and other inflammatory factors (secondary outcomes) signaling pathway will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201612045623N95**

Registration date: **2016-12-04, 1395/09/14**

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

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

Update count: **1**

##### Registration date

2016-12-04, 1395/09/14

##### 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

2016-11-15, 1395/08/25

##### Expected recruitment end date

2016-12-10, 1395/09/20

##### 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 involved in inflammation signaling pathway 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 aged 18 to 40 years

**Exclusion criteria:**

Taking selenium supplements before the intervention  
Needing insulin therapy Placenta abruption Pre-eclampsia Eclampsia Hypo and hyperthyroidism Smokers

**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**

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 research, Arak University of Medical Sciences, Sardasht Avenue, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Approval date**

2016-11-14, 1395/08/24

**Ethics committee reference number**

IR.ARAKMU.REC.1395.308

**Health conditions studied****1****Description of health condition studied**

Gestational diabetes

**ICD-10 code**

E28.2

**ICD-10 code description**

Diabetes mellitus in pregnancy, unspecified

**Primary outcomes****1****Description**

TNF- $\alpha$

**Timepoint**

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

**Method of measurement**

PCR-RT

**Secondary outcomes****1****Description**

IL-1

**Timepoint**

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

**Method of measurement**

PCR-RT

**2****Description**

IL-8

**Timepoint**

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

**Method of measurement**

PCR-RT

**3****Description**

TGF-B

**Timepoint**

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

**Method of measurement**

PCR-RT

**4****Description**

VEGF

**Timepoint**

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

**Method of measurement**

PCR-RT

**Intervention groups****1****Description**

Intervention group: 200 µg selenium (Nature Made, California, USA), once a day, for 6 weeks orally.

**Category**

Treatment - Drugs

**2****Description**

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

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kosar Clinic

**Full name of responsible person**

Mehri Jamilian

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Emam Khomeyni Avenue, Arak

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**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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**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**

Nutritionist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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Isfahan

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## 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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**Web page address****Other areas of specialty/work**

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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

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

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**Position**

PhD of Nutrition

**Latest degree**

Ph.D.