

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- α (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)

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Email address

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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

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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- α

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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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

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Full name of responsible person

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Position

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Latest degree

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