

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of selenium supplementation on insulin resistance, oxidative stress and inflammatory factors in women with gestational diabetes

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The aim of this study is to determine the effects of selenium supplementation on insulin resistance, inflammatory factor and biomarkers of oxidative stress in gestational diabetes.

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

Update count: **1**

Registration date

2014-03-25, 1393/01/05

Design

Double-blind randomized controlled clinical trial.

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Settings and conduct

Seventy patients with gestational diabetes mellitus among pregnant women of eligible and referred to maternity clinics affiliated with the Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Participants/Inclusion and exclusion criteria

Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation will be included in this study. Women with intrauterine fetal death (IUFD), premature preterm rupture of membrane (PPROM), placenta abruption, preeclampsia, eclampsia, chronic hypertension, hypo- or hyperthyroidism, urinary tract infection, smokers, and those with kidney or liver diseases or those taking estrogen therapy, women who required commencing insulin therapy and stressful life conditions will be excluded from the present study.

Expected recruitment start date

2014-03-18, 1392/12/27

Expected recruitment end date

2014-05-16, 1393/02/26

Intervention groups

Patients will be assigned to receive either selenium supplement (intervention group) or placebo (control group).

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Fasting plasma glucose (FPG), insulin resistance, serum insulin, hs-CRP levels, nitric oxide, lipid profiles, biomarkers of oxidative stress and blood pressure

Trial completion date

empty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201403175623N18**

Registration date: **2014-03-25, 1393/01/05**

Scientific title

Effect of selenium supplementation on insulin resistance, oxidative stress and inflammatory factors in women with gestational diabetes

Public title

Effect of selenium in treatment of gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged 18-40 years Pregnant women diagnosed with gestational diabetes mellitus 24-28 weeks' gestation

Exclusion criteria:

Intrauterine fetal death Premature preterm rupture of membrane Placenta abruption Preeclampsia Eclampsia Chronic hypertension Hypo- or hyperthyroidism Urinary tract infection Smokers Kidney or liver diseases Those taking estrogen therapy Stressful life conditions

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after balanced block randomization, subjects will be randomly divided into two groups to take either selenium supplementation (n = 35) or placebo (n = 35). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the maternity clinics affiliated with the Arak University of Medical Sciences, Arak, Iran, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Vice-chancellor for Education and Research, Sardasht Avenue, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2014-03-17, 1392/12/26

Ethics committee reference number

12-160-92

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

Insulin resistance

Timepoint

Baseline and End-of-trial

Method of measurement

Calculation using HOMA formula

Secondary outcomes

1

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

2

Description

Total cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

3

Description

Triglycerides

Timepoint

Baseline and End-of-trial
Method of measurement
Enzymatic kit

4

Description
HDL

Timepoint
Baseline and End-of-trial

Method of measurement
Enzymatic kit

5

Description
LDL

Timepoint
Baseline and End-of-trial

Method of measurement
Enzymatic kit

6

Description
High-sensitivity C-reactive protein

Timepoint
Baseline and End-of-trial

Method of measurement
Elisa kit

7

Description
Nitric oxide

Timepoint
Baseline and End-of-trial

Method of measurement
Spectrophotometry

8

Description
Malondialdehyde

Timepoint
Baseline and End-of-trial

Method of measurement
Spectrophotometry

9

Description
Glutathione

Timepoint
Baseline and End-of-trial

Method of measurement
Spectrophotometry

10

Description
Total antioxidant capacity

Timepoint
Baseline and End-of-trial

Method of measurement
Spectrophotometry

11

Description
Systolic blood pressures

Timepoint
Baseline and End-of-trial

Method of measurement
Sphygmomanometer

12

Description
Diastolic blood pressure

Timepoint
Baseline and End-of-trial

Method of measurement
Sphygmomanometer

Intervention groups

1

Description
Intervention group: Selenium capsule, 200 µg, daily for 6 weeks orally.

Category
Treatment - Drugs

2

Description
Control group: Placebo capsule, daily for 6 weeks orally.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
maternity clinics affiliated with the Arak University of Medical Sciences, Arak, Iran

Full name of responsible person
Dr Meri Jamilian

Street address
Sardasht Ave, Arak

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3819693345

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiei

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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

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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Position

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Latest degree

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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