

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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

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Tehran

Province

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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-γ 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

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Akbarabadi Hospital, Mowlavi Street, Tehran

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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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

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

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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