

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

To survey the effects of selenium supplementation on glucose homeostasis in women with GDM referred to Hafez hospital

Protocol summary

Summary

The present study is designed with the aim of investigating the effect of selenium supplementation on glucose homeostasis in women with gestational diabetes mellitus (GDM). This is a prospective randomized, double blind Placebo-controlled, clinical trial. The study will be performed on pregnant women with GDM who are referred to outpatients clinic of Hafez hospital. Women will be randomly assigned to take either 200 µg selenium supplements as tablet or placebo daily for 12 weeks since 24 to 28 week of gestation. The primary outcomes are the glucose homeostasis changes including fasting plasma glucose (FPG), 2-h OGTT (oral glucose tolerance test), and HbA1C at initial and 3 months after intervention. In addition, we consider body mass index (BMI) as secondary outcomes. Finally, we will compare the results between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041933297N1**

Registration date: **2017-05-06, 1396/02/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-06, 1396/02/16

Registrant information

Name

Mina Rezvannia

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3820 2362

Email address

rezvannia_m@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To survey the effects of selenium supplementation on glucose homeostasis in women with GDM referred to Hafez hospital

Public title

Effects of selenium supplementation on glucose homeostasis in women with GDM

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women diagnosed with gestational diabetes mellitus; Aged 18-40 years old.

Exclusion criteria: Patients on oral hypoglycemic agents; Patients who received insulin.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences, Zand St, Shiraz

City

Shiraz

Postal code

Approval date

2016-09-21, 1395/06/31

Ethics committee reference number

IR.SUMS.MED.REC.1395.13

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus in pregnancy

Primary outcomes

1

Description

Fasting plasma glucose

Timepoint

Before intervention - 3 months after intervention

Method of measurement

Glucometer

2

Description

2 hours oral glucose tolerance test

Timepoint

Before intervention - 3 months after intervention

Method of measurement

Glucometer

3

Description

Hemoglobin A1c

Timepoint

Before intervention - 3 months after intervention

Method of measurement

Chromatographic

Secondary outcomes

1

Description

Body Mass Index

Timepoint

Before intervention - 3 months after intervention

Method of measurement

By BMI Formula

Intervention groups

1

Description

Intervention group: 200 µg selenium supplements daily for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: one placebo tablet daily for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Clinic of Shiraz university of Medical Sciences

Full name of responsible person

Mina Rezvannia

Street address

Chamran Blvd, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University Of medical Science

Full name of responsible person

Dr Seyed Baser Hashemi

Street address

Building of Shiraz University of Medical Sciences, Zand Ave

City

Shiraz

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, Shiraz University Of medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mina Rezvannia

Position

Resident of obstetrics and gynecology

Other areas of specialty/work**Street address**

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Postal code**Phone**

+98 71 3233 2365

Fax**Email**

rezvannia_m@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mina Rezvannia

Position

Resident of obstetrics and gynecology

Other areas of specialty/work**Street address**

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Postal code**Phone**

+98 71 3233 2365

Fax**Email**

rezvannia_m@sums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mina Rezvannia

Position

Resident of obstetrics and gynecology

Other areas of specialty/work**Street address**

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Postal code**Phone**

00

Fax**Email****Web page address**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty