Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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
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Person responsible for updating data

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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