Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Clinical trial of the effect of selenium supplementation compared with the placebo on metabolic profiles in pregnant women at risk for intrauterine growth restriction

Protocol summary

Study aim
The aim of this study is to determine the effects of selenium supplementation on metabolic profiles in pregnant women at risk for intrauterine growth restriction.

Design
Study design: Parallel double-blind (both participants and researchers) randomized controlled clinical trial.

Settings and conduct
Sixty pregnant women at risk for intrauterine growth restriction of eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected. Fasting blood samples will be taken at baseline and after 10-wk intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women at risk for intrauterine growth restriction and aged 18 to 40 years will be included in this study. Exclusion criteria: Taking selenium supplements during past 3 months, Hypo- and hyperthyroidism, Urinary tract infection, Pre-eclampsia, Hypertension, Diseases related to increased inflammation, Smokers and Kidney or liver diseases.

Intervention groups
Intervention group: Selenium supplement (Nature Made, California, USA, 100 µg, daily, for 10 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily, for 10 weeks orally.

Main outcome variables
Biomarkers of oxidative stress and Pulsatility Index (primary outcomes) and lipid profiles, markers of insulin metabolism and inflammatory factors (secondary outcomes)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201601045623N64**
Registration date: **2016-01-31, 1394/11/11**
Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**
Update count: **1**

Registration date
2016-01-31, 1394/11/11

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 36 1534 3570

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date
2015-12-23, 1394/10/02

Expected recruitment end date
2016-01-23, 1394/11/03

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 metabolic profiles in pregnant women at risk for intrauterine growth restriction

Public title
Effect of supplementation in treatment of pregnant women at risk for intrauterine growth restriction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women at risk for intrauterine growth restriction Aged 18 to 40 years

Exclusion criteria:
Taking selenium supplements during past 3 months Hypo- and hyperthyroidism Urinary tract infection Pre-eclampsia Hypertension Diseases related to increased inflammation Smokers Kidney or liver diseases

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To decrease potential confounding effects, all participants will have stratified randomization according to BMI and age. Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups. https://stattrek.com/statistics/random-number-generator.aspx

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 Naghavi Clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules. Supplements and placebo are in the same packaging at the Barij Essence pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Approval date
2015-12-22, 1394/10/01

Ethics committee reference number
IR.Kaums.REC.1394.131

Health conditions studied

1

Description of health condition studied
Pregnancy

ICD-10 code
O94

ICD-10 code description
Sequelae of complication of pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Total antioxidant

Timepoint
At the beginning of the study and after 10 weeks of intervention

Method of measurement
Spectrophotometry

2

Description
Glutathione

Timepoint
At the beginning of the study and after 10 weeks of intervention

Method of measurement
Spectrophotometry

3

Description
Pulsatility index
Timepoint
At the beginning of the study and after 10 weeks of intervention
Method of measurement
Sonography

Secondary outcomes

1

Description
Insulin
Timepoint
At the beginning of the study and after 10 weeks of intervention
Method of measurement
Elisa kit

2

Description
Nitric oxide
Timepoint
At the beginning of the study and after 10 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
hs-CRP
Timepoint
At the beginning of the study and after 10 weeks of intervention
Method of measurement
Elisa kit

4

Description
Triglycerides
Timepoint
At the beginning of the study and after 10 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
Cholesterol
Timepoint
At the beginning of the study and after 10 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 10 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
HDL
Timepoint
At the beginning of the study and after 10 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 10 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: Selenium supplement (Nature Made, California, USA, 100 µg, daily, for 10 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), daily, for 10 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Zatollah Asemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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research@kaums.ac.ir
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, Kashan 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
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Person responsible for updating data

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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