

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The effect of Selenium supplementation on clinical outcomes of Preeclampsia, metabolic profiles, and Pulsatility Index (PI) of uterine artery in Doppler sonography in high risk mothers screening with Quadruple tests

Protocol summary

Study aim

Determining the Complementary Effect of Selenium on clinical outcomes of Preeclampsia, metabolic profiles, and Pulsatility Index (PI) of uterine artery in Doppler sonography in high risk mothers screening with Quadruple tests

Design

Study design: Random clinical trial of two blind sides (both patients and researchers) with parallel groups, Phase 2 in 60 patients. Randomization is done using Stat Trek software and based on random number methods.

Settings and conduct

Among high-risk pregnant women for preeclampsia, screened with Quadruple tests, 60 patients will be selected based on study criteria. Participants as well as researchers or evaluators are unaware of the allocation of study groups. Complementary and placebo capsules are similar in shape and size. This study will be performed at Beheshti Hospital in Kashan.

Participants/Inclusion and exclusion criteria

Entry conditions: Pregnant women at high risk for preeclampsia who have been screened with Quadruple tests, in the range of 18 to 40 years old and living in Kashan, with the first and single pregnancies and the absence of bone and chromosomal fetal abnormalities will enter the study after completing the consent form. No entry conditions: Lack of willingness to cooperate at any stage of the project

Intervention groups

Intervention group: 200 micrograms of selenium capsules, 1 daily, orally for 12 weeks. Control group: Selenium placebo capsules, 1 daily, orally for 12 weeks.

Main outcome variables

Highly sensitive C-reactive protein (Hs-CRP) (Initial consequence) : Systolic and diastolic blood pressure levels : Nitric Oxide : Glutathione : Total antioxidants :

Malone De Aldeid : Serum hemoglobin : Serum Platelet : Liver transaminases : Serum Creatinine : Serum Uric acid : pulsatility Index of Uterine artery (PI) : Body Mass Index (BMI) : Urinary protein excretion (Secondary consequence) .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047701N1**

Registration date: **2020-06-26, 1399/04/06**

Registration timing: **prospective**

Last update: **2020-06-26, 1399/04/06**

Update count: **0**

Registration date

2020-06-26, 1399/04/06

Registrant information

Name

Farah Shahin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3664 0642

Email address

shahin-f@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-20, 1399/04/30

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Selenium supplementation on clinical outcomes of Preeclampsia, metabolic profiles, and Pulsatility Index (PI) of uterine artery in Doppler sonography in high risk mothers screening with Quadruple tests

Public title

The effect of Selenium supplementation in high risk mothers for Preeclampsia screened with Quadruple tests

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

High-risk pregnant women for pre-eclampsia screened with Quadruple tests
Age of 18 to 40
Pregnant woman living in Kashan
First pregnancy
Single pregnancy
Lack of bone and chromosomal abnormalities
Complete the consent form

Exclusion criteria:

Lack of willingness to cooperate at any stage of the project
Under age of 18 years old
Pregnant women who are currently smoking (Low risk for preeclampsia)
Pregnant women who are taking selenium supplements
Pregnant women who are taking thyroid medication
Pregnant women who are taking Aspirin, Heparin or Anti hypertensive drugs
Pregnant women who have chronic proteinuria
Abnormal scan anomalies

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization is done using Stat Trek software and based on random number methods. In this method, the computer selects random numbers. Accounting is done by considering numbers for two groups. For example, even numbers will be in the intervention group and individual numbers will be in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and random allocation of researchers and

participants in the study will remain hidden until the completion of statistical analysis. Another person in the clinic, who has no role in this clinical trial and is unaware of the random allocation, will assign the numbered bottles of the capsules to the study participants. Patients and researchers are unaware of the type of intervention, and after analyzing the data, the package codes are decrypted.

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

Qutb Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2020-05-18, 1399/02/29

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.008

Health conditions studied**1****Description of health condition studied**

Pre-eclampsia

ICD-10 code

O14

ICD-10 code description

Pre-eclampsia

Primary outcomes**1****Description**

Highly sensitive C-reactive protein (Hs-CRP)

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Eliza Kit

Secondary outcomes

1

Description

Systolic and diastolic blood pressure levels

Timepoint

At the beginning of the study and then twice a week

Method of measurement

Mercury sphygmomanometer

2

Description

Nitric Oxide

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

3

Description

Glutathione

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

4

Description

Total antioxidants

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

5

Description

Malone De Aldeid

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

6

Description

pulsatility Index of Uterine artery

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Caller Doppler ultrasound

7

Description

Serum hemoglobin

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

laboratory kit

8

Description

Serum Platelet

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

laboratory kit

9

Description

Liver transaminases

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

laboratory kit

10

Description

Serum Creatinine

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

laboratory kit

11

Description

Serum Uric acid

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

laboratory kit

12

Description

Body Mass Index (BMI)

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Weight by scales , Height by meter

13

Description

Urinary protein excretion

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Urine sample

Intervention groups

1

Description

Intervention group:200 micrograms of selenium capsules (Alpha Vitamins , Arian Sena , Tehran , Iran),1 daily, orally for 12 weeks . Intervention duration: 12 weeks .

Category

Treatment - Drugs

2

Description

Control group: Selenium placebo capsules (Barij Essence , Kashan , Iran) , 1 daily, orally for 12 weeks. Intervention duration: 12 weeks .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Clinic of Shahid Beheshti Hospital

Full name of responsible person

Farah Shahin

Street address

Women's Clinic, Shahid Beheshti Hospital, Qutb Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5554 0026

Email

farahshahin660@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafsheh

Street address

Qutb Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Phone

+98 31 5554 2999

Email

banafshe57@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Farah Shahin

Position

Resident of obstetrics and gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Qutb Ravandi Boulevard , Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Phone

+98 31 5554 0021

Email

farahshahin660@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Farah Shahin

Position

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Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Phone

+98 31 5554 0021

Email

farahshahin660@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Farah Shahin

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Email

farahshahin660@yahoo.com

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