Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison the efficacy of selenium on preventing preeclampsia in pregnant women

Protocol summary

Summary

The purpose of this study is to determine the effect of selenium on prevention of preeclampsia in pregnant women. Inclusion criteria: singleton pregnancy, gestational age 24 weeks, willingness to participate in this study, body mass index of 19 to 30 and an increase of at least 4 kg during the first 6 months of pregnancy. Exclusion criteria: abnormal ultrasonography, the risk of chronic diseases, alcohol and tobacco use. From June 2015 to June 2016 in a controlled clinical trial, 270 women will randomly divide into two groups. The target group from 24 to 40 weeks of pregnancy will get 200 micro grams of selenium per day. The control group will not get any medications. At the end the incidence of preeclampsia in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506034339N9**
Registration date: **2015-08-01, 1394/05/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-01, 1394/05/10

Registrant information

Name
Elham Rahmani
Name of organization / entity
Bushehr University of Medical Sciences
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Iran (Islamic Republic of)
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+98 77125265914
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rahmani@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellery for Research of Bushehr University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of selenium on preventing preeclampsia in pregnant women

Public title

The effect of selenium on preventing pregnancy induced hypertension

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Singleton pregnancy; gestational age of 24 weeks; willingness to participate in the study; body mass index of 19 to 30 and at least 4 kg during the first 6 month of pregnancy weight gain as well. Exclusion criteria: Abnormal fetal ultrasound; the risk of chronic disease such as diabetes and hypertension; hypertension drugs requirement; chronic and sever illness of the kidney; adrenal, thyroid and parathyroid; cardiovascular; infection; malignancies, immune system disorders; use of alcohol and tobacco; severe stress in pregnancy period; consumption anti-cancer drugs; aspirin; anticoagulants; daily using over 60 mg of iron; daily using calcium and

consumption of zinc.

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **270**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Bushehr University of Medical Sciences

Street address
Bushehr University of Medical Sciences, Moallem Street, Bushehr

City
Bushehr

Postal code
7514633341

Approval date
2015-05-18, 1394/02/28

Ethics committee reference number
bpums.rec.1394.7

Health conditions studied

1

Description of health condition studied
Preeclampsia

ICD-10 code
O10

ICD-10 code description
Pre-existing hypertension complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Hypertension

Timepoint
24 weeks and 32 weeks of gestational age and delivery time

Method of measurement
mmHg and with Sphygmomanometer

Secondary outcomes

1

Description
urine protein

Timepoint
24wks , 32wks , delivery time

Method of measurement
urinaryanalysis

Intervention groups

1

Description
Pregnant women from 24 to 40 weeks of pregnancy (duration:16 weeks) will get 200 micrograms of selenium per day orally.

Category
Treatment - Drugs

2

Description
Pregnant women from 24 to 40weeks of pregnancy (duration: 16 weeks) based on study criteria will not get any medication.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohadaye Khalije Fars Hospital

Full name of responsible person
Elham Rahmani

Street address
Shohada Khalije Fars Hospital, Taleghani Street, Azadi Square, Bushehr, Iran

City
Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellery for Research of Bushehr University of Medical Sciences

Full name of responsible person
Afshin Ostovar

Street address
Bushehr University of Medical Sciences, Alamdar St, Salman Farsi St, Bushehr, Iran.

City
Bushehr

Grant name

Grant code / Reference number

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

Title of funding source
Vice-chancellery for Research of Bushehr University of Medical Sciences

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
Bushehr University of Medical Sciences

Full name of responsible person
Elham Rahmani

Position
Associate professor of clinical obstetrics and gynecology and fellowship of infertility

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Web page address

Person responsible for updating data

Contact

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