

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

Country

Iran (Islamic Republic of)

Phone

+98 77125265914

Email address

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

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Elham Rahmani

Position

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Other areas of specialty/work

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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