

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The incidence risk of preeclampsia in pregnant women treated with selenium supplementation versus placebo: a randomized double-blind placebo-controlled trial

#### Protocol summary

##### Summary

Objectives: To assess the incidence risk of preeclampsia in pregnant women treated with selenium supplementation versus placebo. Design: a double blind randomized clinical trial. Setting and conduct: The eligible pregnant women who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Primigravid; first trimester. Exclusion criteria: Using selenium supplementation during past year; using any medications except ferrous sulfate and folic acid; thyroid disease; diabetes; hypertension; infective diseases; diet full of selenium. Intervention group: Selenium supplementation 100 mgr once a day until the end of pregnancy. Control group: Placebo once a day until the end of pregnancy. Primary outcome: Measuring systolic and diastolic blood pressure before intervention and at the end of pregnancy through physical examination. Randomization: The patients will be randomly assigned to the intervention and control groups through drawing lot. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201702109014N143**  
Registration date: **2017-02-20, 1395/12/02**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-20, 1395/12/02

#### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice-chancellor for Research the Technology, Hamadan  
University of Medical Sciences

#### Expected recruitment start date

2017-02-19, 1395/12/01

#### Expected recruitment end date

2017-11-22, 1396/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The incidence risk of preeclampsia in pregnant women treated with selenium supplementation versus placebo: a randomized double-blind placebo-controlled trial

#### Public title

The incidence risk of preeclampsia in pregnant women treated with selenium supplementation versus placebo

#### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: Primigravid; first trimester. Exclusion criteria: Using selenium supplementation during past year; using any medications except ferrous sulfate and folic acid; thyroid disease; diabetes; hypertension; infective diseases; diet full of selenium.

## **Age**

No age limit

## **Gender**

Female

## **Phase**

2

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **158**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

Randomization: The patients will be randomly assigned to the intervention and control groups through drawing lot. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

##### **Street address**

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### **City**

Hamadan

##### **Postal code**

6517838695

#### **Approval date**

2016-11-10, 1395/08/20

#### **Ethics committee reference number**

IR.UMSHA.REC.1395.362

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Pre-eclampsia

#### **ICD-10 code**

O14.9

#### **ICD-10 code description**

Pre-eclampsia, unspecified

## **Primary outcomes**

### 1

#### **Description**

Measuring systolic and diastolic blood pressure

#### **Timepoint**

before intervention and at the end of pregnancy

#### **Method of measurement**

through physical examination

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Selenium supplementation 100 mgr once a day until the end of pregnancy.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Placebo once a day until the end of pregnancy.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Fatemieh Hospital

##### **Full name of responsible person**

Dr Fatemeh Mohsenpour

##### **Street address**

Fatemieh Hospital, Pasdaran Ave.

##### **City**

Hamadan

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**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 the Technology, Hamadan  
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**

Fatemieh Hospital

**Full name of responsible person**

Dr Fatemeh Mohsenpour

**Position**

Resident of Gynecology

**Other areas of specialty/work**

**Street address**

Fatemieh Hospital, Pasdaran Ave.

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+98 81 3828 3939

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**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Fatemieh Hospital

**Full name of responsible person**

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**Position**

Resident of Gynecology

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

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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*