

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effect of L-arginine versus placebo on intrauterine growth of the fetus in primigravid women: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of L-arginine versus placebo on intrauterine growth of the fetus in primigravid women

##### Design

This is a randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

##### Settings and conduct

This study will be performed in the Fatemieh Hospital in Hamadan city on 150 primigravid women. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 40 years; Prime gravid; Singleton pregnancy; Gestational age between 16 to 20 weeks; Exclusion criteria: Chronic illness such as diabetes or hypertension; Selenium supplementation

##### Intervention groups

Intervention group: Routine care during pregnancy plus 1000 mg L-arginine capsule (manufactured by Karen Pharmaceutical Co.) daily from 20th week of pregnancy for 12 weeks Control group: Just routine care during pregnancy

##### Main outcome variables

Primary outcome: Internal uterine growth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N419**

Registration date: **2022-03-15, 1400/12/24**

Registration timing: **prospective**

Last update: **2022-03-15, 1400/12/24**

Update count: **0**

##### Registration date

2022-03-15, 1400/12/24

##### 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

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-04, 1401/01/15

##### Expected recruitment end date

2023-02-19, 1401/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of L-arginine versus placebo on intrauterine growth of the fetus in primigravid women: a randomized clinical trial

##### Public title

Effect of L-arginine versus placebo on intrauterine growth of the fetus in primigravid women

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Age 18 to 40 years; Prime gravid; Singleton pregnancy;  
Gestational age between 16 to 20 weeks;

### **Exclusion criteria:**

Chronic illness such as diabetes or hypertension;  
Selenium supplementation

## **Age**

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

## **Gender**

Female

## **Phase**

3

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **150**

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

Randomized

## **Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

## **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**

Ethics Committee of Hamadan University of Medical Sciences

##### **Street address**

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

##### **City**

Hamadan

##### **Province**

Hamadan

##### **Postal code**

6517838695

#### **Approval date**

2022-03-05, 1400/12/14

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

IR.UMSHA.REC.1400.970

## **Health conditions studied**

### **1**

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

Intrauterine growth

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

P05.9

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

Newborn affected by slow intrauterine growth,  
unspecified

## **Primary outcomes**

### **1**

#### **Description**

Internal uterine growth

#### **Timepoint**

From the 20th week of pregnancy to the end of  
pregnancy

#### **Method of measurement**

By measuring uterine height and ultrasound monthly

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Routine care during pregnancy plus  
1000 mg L-arginine capsule (manufactured by Karen  
Pharmaceutical Co.) daily from 20th week of pregnancy  
for 12 weeks

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Just routine care during pregnancy

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Fatemieh Hospital in Hamadan city

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

Razieh Darabi

##### **Street address**

Fatemieh Hospital, Pasdaran Ave.

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Reza Shokoohi  
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Hamadan University of Medical Sciences, Shahid Fahmideh Ave  
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info.research@umsha.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Hamedan 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**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Razieh Darabi  
**Position**  
Medical Student  
**Latest degree**

Medical doctor  
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General Practitioner  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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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