

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

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Name of organization / entity

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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

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Postal code

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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

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Sponsors / Funding sources

1

Sponsor

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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

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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