Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of L-arginine versus control group on the prevention of preeclampsia in primiparous pregnant women: a single-blind randomized controlled trial

Protocol summary

Study aim
To assess the effect of L-arginine versus control group on the prevention of preeclampsia in primiparous pregnant women

Design
This is a single-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

Settings and conduct
This study will be performed in the Fatemieh Hospital in Hamadan city on 172 primiparous pregnant women. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 45 years; Primiparous: Singleton; Gestational age of 20 weeks; Exclusion criteria: History of hypertension; Affected with chronic diseases such as thyroid disorder and diabetes; Using selenium supplement;

Intervention groups
Intervention group: Supplements (iron tablets and multivitamin capsules and calcium tablets) from 16th weeks of pregnancy once a day for 16 weeks plus L-arginine 500 mg tablets (manufactured by Karen Pharmaceutical Co.) from 20th weeks of pregnancy once a day for 12 weeks Control group: Supplements (iron tablets and multivitamin capsules and calcium tablets) from 16th weeks of pregnancy once a day for 16 weeks

Main outcome variables
Primary outcome: Preeclampsia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N416**
Registration date: **2022-01-12, 1400/10/22**
Registration timing: **prospective**

Last update: **2022-01-12, 1400/10/22**
Update count: **0**

Registration date
2022-01-12, 1400/10/22

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-30, 1400/11/10

Expected recruitment end date
2023-01-30, 1401/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of L-arginine versus control group on the prevention of preeclampsia in primiparous pregnant women: a single-blind randomized controlled trial

Public title
Effect of L-arginine versus control group on the prevention of preeclampsia in primiparous pregnant women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 45 years; Primiparous: Singleton; Gestational age of 20 weeks;
Exclusion criteria:
History of hypertension; Affected with chronic diseases such as thyroid disorder and diabetes; Using selenium supplement;
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **172**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single -blind.
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
2021-10-16, 1400/07/24
Ethics committee reference number
IR.UMSHA.REC.1400.538

Health conditions studied

1

Description of health condition studied
Pre-eclampsia
ICD-10 code
O14
ICD-10 code description
Pre-eclampsia

Primary outcomes

1

Description
Preeclampsia
Timepoint
Every two weeks until the end of pregnancy
Method of measurement
By taking a history (headache, blurred vision, epigastric pain, seizures), clinical examination (hypertension) and laboratory methods (oliguria, proteinuria, and increased liver enzymes)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Supplements (iron tablets and multivitamin capsules and calcium tablets) from 16th weeks of pregnancy once a day for 16 weeks plus L-arginine 500 mg tablets (manufactured by Karen Pharmaceutical Co.) from 20th weeks of pregnancy once a day for 12 weeks
Category
Treatment - Drugs

2

Description

Control group: Supplements (iron tablets and multivitamin capsules and calcium tablets) from 16th weeks of pregnancy once a day for 16 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Dr. Shahedeh Khansari

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

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6517838695

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+98 81 3828 3939

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dr_sh_kh@yahoo.com

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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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

Dr. Shahedeh Khansari

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr. Jalal Poorolajal

Position
Professor of Epidemiology

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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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