Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the Effectiveness of l_arginine plus aspirin with aspirin alone in preventing adverse outcomes in pregnant women at high risk of preeclampsia

Protocol summary

Study aim
Determining the effect of L-arginine with aspirin and aspirin alone in preventing adverse outcomes in pregnant mothers with high risk of preeclampsia

Design
Clinical trial with a control group, triple blind, randomized, phase 3 on 90 patients. Randomization is done by Permuted block randomization method.

Settings and conduct
Identifing pregnant women referred to the Beheshti clinic in Kashan during the years 2022-2023, at risk of pre-eclampsia with gestational age 28-12 weeks. Allocating them in two groups by random block method and using Random generator software. Both groups will receive drug in the same packaging, size and box. The codes will be left with one of the collaborators of the research project and will be decoded at the end. None of the presenters and patients have any knowledge of the type of codes of each patient until after the data analysis, thus it is triple blind.

Participants/Inclusion and exclusion criteria
Pregnant women at risk of pre-eclampsia include: previous history of pre-eclampsia in the individual or first-degree family, autoimmune disease, diabetes, chronic hypertension, age over 35 years, and body mass index greater than 30; nulligravida; multiple pregnancy; lipid disorders and age of 12 to 28 weeks of pregnancy will be included in the study.The presence of drug sensitivity to aspirin or L-arginine, or the presence of any fetal disorder or contraindication to continue the pregnancy, will be excluded from the study.

Intervention groups
L-arginine 1000 mg daily with Aspirin 80 mg were prescribed in the intervention group from 12 to 28 weeks until the end of pregnancy, and in the control group aspirin 80 mg daily with placebo will be prescribed, thus the effect of L-arginine will be investigated in comparison with placebo.

Main outcome variables
Pregnancy complications; preeclampsia; post partom hemorrhage; preterm delivery; placental abruption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221108056440N1**
Registration date: **2022-11-27, 1401/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-27, 1401/09/06**
Update count: **0**

Registration date
2022-11-27, 1401/09/06

Registrant information

Name
NAFISEH KHALILI

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 6673 0476

Email address
nafiseh77khalili@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of l_arginine plus aspirin with aspirin alone in preventing adverse outcomes in pregnant women at high risk of preeclampsia

Public title

Comparison between L-arginine and aspirin and aspirin alone in preventing preeclampsia in high-risk pregnant women.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women who are at high risk for preeclampsia Pregnant women with a gestational age between 14 and 28 weeks of pregnancy Previous history of pre-eclampsia in the individual or first degree relatives of the individual's sister or mother Women with a history of chronic hypertension Body mass index greater than 30 Multiple pregnancy Lipid disorders

Exclusion criteria:

Drug sensitivity to L-arginine Drug sensitivity to aspirin

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: all the 4 blocks containing two letters A and B are prepared (6 blocks) and we assign a number from 1 to 6 to each of them. Then, using the table of random numbers, numbers one to six are selected (24 numbers) and the corresponding block will be written based on the selected random number. With this, a sequence of 90 letters A and B will be obtained. Each of the samples will have a number from 1 to 90 when introducing the study, and based on each person's number, they will receive an A or B code based on the list of letters. This is done randomly and both groups will be almost the same. Group A was assigned to the group receiving L-arginine and aspirin by simple random method, and group B was assigned to the group receiving aspirin and placebo. With this method, 45 patients are placed in each group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Both groups receive drugs in the same package, size and box. The codes remain with one of the collaborators of the research project and will be decoded at the end of the study. None of the presenters and patients know the type of codes of each patient until after the data analysis, thus this study is conducted triple blinded.

Placebo

Used

Assignment

Parallel

Other design features

Permuted block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Parastar Ave., 5th of Qotb_e Ravandi Blvd., Kashan, IRAN

City

Kashan

Province

Isfehan

Postal code

8715973446

Approval date

2022-11-01, 1401/08/10

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.135

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O14

ICD-10 code description

Pre-eclampsia

2

Description of health condition studied

Diabetes Mellitus

ICD-10 code

O24

ICD-10 code description

Diabetes mellitus in pregnancy, childbirth, and the puerperium

3

Description of health condition studied
Hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Blood Pressure
Timepoint
During the first appointments and at each pregnancy care visit (for visits during pregnancy, it is once a month from the first week to 28 weeks, and every two weeks from 28 to 36 weeks and then weekly examination until the end of pregnancy).
Method of measurement
The percentage of people with blood pressure above 90.140 mm Hg.

2

Description
preeclampsia
Timepoint
From the 20th week of pregnancy during any pregnancy care as discussed above or if there are any signs and symptoms of preeclampsia from the 20th week onwards.
Method of measurement
Checking blood pressure and other signs and symptoms of pre-eclampsia, including headache, blurred vision, chest pain or laboratory disorders such as thrombocytopenia or increased liver enzymes or increased creatinine.

Secondary outcomes

1

Description
Termination of pregnancy (term or pre-term)
Timepoint
At the end of pregnancy
Method of measurement
With the birth of a baby and during childbirth

2

Description
IUGR
Timepoint
During pregnancy care, especially during the 28th till 32nd weeks and at the time of birth
Method of measurement
Measurement of fetal weight and growth during pregnancy and birth weight

3

Description
pregnancy complication
Timepoint
During pregnancy and childbirth
Method of measurement
Examination in terms of the amount of bleeding, meconium, decollement, stillbirth, preterm labour

Intervention groups

1

Description
Intervention group: L-arginine 1000 mg along with aspirin 80 mg will be prescribed once a day for pregnant women who are among the high-risk group for preeclampsia, .
Category
Treatment - Drugs

2

Description
Control group: In this group of pregnant women, who are among the high-risk group for eclampsia, aspirin 80 mg once a day will be routinely prescribed
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital of Medical Sciences, Kashan
Full name of responsible person
Nafiseh Khalili
Street address
Qotb-e Ravandi Blvd, Isfahan Province, Kashan, 2C94+6G5
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87159 88111
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Fax
Email
beheshtihospital@kaums.ac.ir
Web page address
http://beheshti.kaums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholam Ali Hamidy
Street address
5th kilometer of Qutb Rawandi Blvd. Kashan University of Medical Sciences - Research Vice-Chancellor
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+98 31 5558 9399
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+98 31 5558 9338
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hamidi_gh@kaums.ac.ir
Web page address
http://research.kaums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Hossein Akbary
Position
Associate professor of Biostaistics
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Biostatistics
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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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NAFISEH KHALILI
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8174618683
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Fax

Email
Nafiseh77khalili@yahoo.com

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