Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Comparative study of the effect of hydralazine and nifedipine on acute hypertension in women with preeclampsia

Protocol summary

Study aim
The aim of this study was to compare the effect of hydralazine and nifedipine on the reduction of acute hypertension in women with preeclampsia in Asali Hospital in Khorramabad.

Design
Clinical trial with control group, one-way blind, randomized, 60 patients in two groups of 30 people,Simple randomization was used

Settings and conduct
60 pregnant women with preeclampsia with a blood pressure of 160 on 110 mm Hg and above, who meet the inclusion criteria after obtaining informed consent will be randomly assigned to the study groups, and in one of two injection groups Hydralazine or oral nifedipine will be administered. Accordingly, in the injection group of hydrolazine, 5 mg of the drug will be injected intravenously and an oral drug that does not contain drug content will be used for blinding. In the nifedipine group, 10 mg tablets up to a maximum of four doses are used if needed, and normal saline intravenous injection is used for blindness.

Participants/Inclusion and exclusion criteria
In this study, inclusion criteria include pregnant women 18 to 45 years, gestational age greater than or equal to 20 weeks, blood pressure greater than or equal to 160 over 110, and exclusion criteria include maternal heart disease (cardiac arrhythmia , heart failure , chest pain, etc.), kidney, liver disease and fetal disorders, including intrauterine growth restriction, oligohydramnios, and uncertain patterns of fetal heart rate.

Intervention groups
The intervention groups will consist of two groups of 30 people with a total of 60 people. In the intervention group number one, to reduce blood pressure, 5 mg of hydralazine will be used intravenously every 20 minutes, and in the intervention group number two, To reduce blood pressure, nifedipine 10 mg orally will be used every 20 minutes.

Main outcome variables
Primary outcome variables include systolic blood pressure and diastolic blood pressure.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090701002114N6**
Registration date: **2020-09-21, 1399/06/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-21, 1399/06/31**
Update count: **0**

Registration date
2020-09-21, 1399/06/31

Registrant information

Name
Fatemeh Yari

Name of organization / entity
Lorestan university of medical sciences

Country
Iran (Islamic Republic of)

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+98 66 1222 6450

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-12, 1399/06/22

Expected recruitment end date
2021-03-12, 1399/12/22

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of hydralazine and nifedipine on acute hypertension in women with preeclampsia

Public title
the effect of hydralazine and nifedipine on hypertension
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women 18 to 45 years old Gestational age greater than or equal to 20 weeks Blood pressure greater than or equal to 160 over 110
Exclusion criteria:
Maternal disease of any kind, including heart (heart arrhythmia - heart failure - chest pain, etc.), kidney, liver Fetal disorders including intrauterine growth restriction (IUGR) and Oligohydramnios Uncertain patterns of fetal heart rate
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be assigned to the study groups in a simple, even and odd manner. The randomization tool will be the use of a random number table in such a way that people in the group of even numbers are characteristic of group one, ie hydralazine, and people with odd numbers in the group. 2 nifedipine will be placed
Blinding (investigator's opinion)
Single blinded
Blinding description
In the group receiving nifedipine, four doses of the drug will be given to the patient according to the instructions and intravenous injection of distilled water will be used to blind the patient. In contrast, in the group receiving hydralazine, the main drug will be injected intravenously at a dose of 5 mg. People in this group will use the placebo in pill form
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences
Street address
Office of Research Ethics Committee, Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences, University Campus Complex, km 3 of Khorramabad Boroujerd Road, Khorramabad
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Approval date
2020-08-05, 1399/05/15
Ethics committee reference number
IR.LUMS.REC.1399.093

Health conditions studied

1

Description of health condition studied
preeclampsia
ICD-10 code
ICD-10 code description
o14

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
At the beginning of the study, then every twenty minutes until the blood pressure drops
Method of measurement
Using electronic blood pressure monitoring device

2

Description
Diastolic blood pressure
Timepoint
At the beginning of the study, then every twenty minutes until the blood pressure drops
Method of measurement
Using electronic blood pressure monitoring device

Secondary outcomes

1

Description
Average blood pressure
Timepoint
At the beginning of the study, then every twenty minutes until the blood pressure drops
Method of measurement
Using electronic blood pressure monitoring device

2

Description
Time to achieve controlled blood pressure
Timepoint
At the beginning of the study, then every twenty minutes
Method of measurement
Used in hours and in minutes

Intervention groups

1

Description
Intervention group: In intervention group number one, which includes receiving hydralazine. 5 mg of this drug will be slowly injected intravenously and to blind the samples in this group, an oral drug that has no drug content will be used. Blood pressure is checked every 20 minutes, and if there is a blood pressure of 160 over 110 mm Hg and more, another dose of the drug is injected.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group number two includes receiving nifedipine, which will be used as a 10 mg tablet. Intravenous distilled water will be used to blind the samples in this group. Blood pressure is checked every 20 minutes and if there is a blood pressure of 160 over 110 mm Hg and more, another dose of the drug is prescribed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Asali hospital
Full name of responsible person
Masoumeh Ghaffarzadeh
Street address
Asali Hospital, 14th Street,Palestine Alley
City
Khorramabad
Province
Lorestan
Postal code
6818795895
Phone
+98 66 3340 6099
Email
asali.hospital@lums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Ibrahim Fallahi
Street address
medical school.,4 km Khorramabad Boroujerd Road.,Kamalvand
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Khorramabad
Province
Lorestan
Postal code
6813833946
Phone
+98 66 3312 0172
Email
falahi.e@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Fatemeh Yari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work

Reproductive Health

Street address

Medical school.,4 km Khorramabad Boroujerd Road.,Kamalvand

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381351698

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

It is possible to share all the data while maintaining the principle of not mentioning the names of individuals

When the data will become available and for how long

One year after the publication of the related article

To whom data/document is available

Researchers of university centers

Under which criteria data/document could be used

The data of the present study can be used after obtaining permission and approval from the Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences

From where data/document is obtainable

Refer to the project manager, Dr. Fatemeh Yari, with email address yari1672@yahoo.com, and contact number 09163613621

What processes are involved for a request to access data/document

After completing the research and publishing the relevant article, individuals can apply to the Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences to receive documents and after obtaining permission from this department, send a confirmation from the Vice Chancellor for Research to the project manager. Can access documentation.

Comments