

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 66 1222 6450

Email address

yari.f@lums.ac.ir

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

City

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

City

Khorramabad

Province

Lorestan

Postal code

381351698

Phone

+98 66 3312 0133

Email

yari.f@lums.ac.ir

Person responsible for scientific 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

City

Khorramabad

Province

Lorestan

Postal code

381351698

Phone

+98 66 3312 0133

Email

yari.f@lums.ac.ir

Person responsible for updating data

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

City

Khoramabad

Province

Lorestan

Postal code

381351698

Phone

+98 66 3312 0133

Email

yari.f@lums.ac.ir

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