Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

The effect of adding lasix to antihypertensive treatment in controlling postpartum hypertension in women with preeclampsia

Protocol summary

Study aim

Determining the effect of adding LASIX to antihypertensive therapy (nifedipine) on the control of postpartum hypertension in women with preeclampsia

Design

randomized clinical trial with control group,Parallel groups, Not Blind, 58 patient in each group

Settings and conduct

This study will be conducted as a clinical trial with the participation of 116 women with postpartum preeclampsia who have high blood pressure and are referred to Mahdieh Hospital. Patients with inclusion criteria were selected as an available sample and then randomly divided into two groups. All women will be treated with nifedipine 10 mg every 8 hours. The static dose of nifedipine 10 mg will be increased each time the blood pressure is greater than 160/110. In the intervention group, in addition to nifedipine, furosemide tablets of 20 mg once daily from 24 hours after delivery until 3 days later will be given. Women in the control group will only be treated with nifedipine.

Participants/Inclusion and exclusion criteria

- Inclusion criteria: • Systolic blood pressure ≥ 150mm Hg • Diastolic blood pressure ≥ 100 mm Hg • Urine rate> 50 ml / h • Termination of magnesium sulfate treatment - Exclusion criteria: • History of chronic hypertension • Use of diuretics • Previous underlying renal disorders • Having diabetes • Hemodynamic instability • Contraindications to the use of Lasix

Intervention groups

All patients will be treated with nifedipine 10 mg every 8 hours. The static dose of nifedipine 10 mg will be increased each time the blood pressure is greater than 160/110. In the intervention group, in addition to nifedipine, furosemide tablets of 20 mg once daily from 24 hours after delivery until 3 days later will be given. Women in the control group will only be treated with nifedipine.

Main outcome variables

Faster control of blood pressure in the postpartum period of patients with preeclampsia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191031045289N2**
Registration date: **2020-08-06, 1399/05/16**
Registration timing: **prospective**

Last update: **2020-08-06, 1399/05/16**
Update count: **0**

Registration date

2020-08-06, 1399/05/16

Registrant information

Name

Zahra Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7748 0345

Email address

n.ghaemi.983@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of adding lasix to antihypertensive treatment in controlling postpartum hypertension in women with preeclampsia

Public title
The effect of adding lasix to antihypertensive treatment in controlling postpartum hypertension in women with preeclampsia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Systolic blood pressure above 150 mm Hg Diastolic blood pressure above 100 mm Hg Urine rate more than 50 cc per hour Termination of treatment with magnesium sulfate
Exclusion criteria:
History of chronic hypertension Blood pressure less than 150/100 mm Hg Use of diuretics Previous underlying renal disorders Having diabetes Hemodynamic instability Contraindications to the use of Lasix Hematocrit more than 37

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **116**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients with inclusion criteria will be selected as available sample and then will be randomly divided into two groups of intervention and non-intervention.

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 Shahid Beheshti University of Medical Sciences
Street address
No 30, East 22 Ave., South allameh St.
City
Tehran
Province
Tehran
Postal code
1997843341

Approval date
2020-05-26, 1399/03/06

Ethics committee reference number
IR.SBMU.MSP.REC.1399.067

Health conditions studied

1

Description of health condition studied
Preeclampsia

ICD-10 code
O15.0

ICD-10 code description
Eclampsia in pregnancy

Primary outcomes

1

Description
Postpartum blood pressure control

Timepoint
From 24 hours to 5 days after delivery

Method of measurement
Mercury sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group will be treated with nifedipine 10 mg every 8 hours. The static dose of nifedipine 10 mg will be increased each time the blood pressure is greater than 160/110. In this group, in addition to nifedipine, furosemide tablets of 20 mg once daily from 24 hours after delivery to 3 days later will be given. If additional medication is needed to control blood pressure, the patient will not be excluded from the study, but this will be recorded in the patient information.

Category
Treatment - Drugs

2

Description
Control group: Patients in this group will be treated with nifedipine 10 mg every 8 hours. The static dose of

nifedipine 10 mg will be increased each time the blood pressure is greater than 110/160. In this group, patients will only be treated with nifedipine. If additional medication is needed to control blood pressure, the patient will not be excluded from the study, but this will be recorded in the patient information.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mahdieh Hospital
Full name of responsible person
Tayebeh Jahed Bozorgan
Street address
Shishegarkhane Ave., Fadaeian Eslam St., Shoush Sq.
City
Tehran
Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
Email
mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Arabi St.
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Pegah Azadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
No. 30, East 22 Ave., South Allameh St.
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Person responsible for scientific inquiries

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Full name of responsible person
Pegah Azadi
Position
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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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Pegah Azadi

Position
Resident

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Medical doctor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All participants' information and study results will be shared after anonymity.

When the data will become available and for how long
After printing the results

To whom data/document is available
It will be available to everyone.

Under which criteria data/document could be used
Use of the data is permitted by citing the source.

From where data/document is obtainable
Dr. Pegah Azadi dr.pegahazadi@gmail.com

What processes are involved for a request to access data/document
Contact Dr. Azadi via the email address provided.

Comments