

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 Mahdiah 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 $\geq$ 150mm Hg • Diastolic blood pressure $\geq$ 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@sbm.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

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pegah Azadi

Position

Resident

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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

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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