

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Assessing the clinical effects of a short-term course of Oral Furosemide in postpartum period in patients with preeclampsia during pregnancy : A Randomized Controlled Trial

Protocol summary

Study aim

Examining the prevalence of persistent hypertension on the 5th day after delivery or the day the patients were discharged from the hospital (whichever occurred earlier)

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial in 118 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The study was conducted in an academic hospital affiliated to Iran University of Medical Sciences. Blinding was performed on the patients. Patients will be randomized and one group will be prescribed only angiotensin inhibitor drugs and the other group will be prescribed furosemide drugs in addition to this drug. The groups will then be compared with each other in terms of specified clinical outcomes

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with recent pregnancy which was complicated with preeclampsia. patients under 18 and those with renal disease or history of hypertension or history of congenital heart defects will be excluded

Intervention groups

Women with recent pregnancy who had high blood pressure during pregnancy. In the intervention group, in addition to the usual treatment, which includes the administration of angiotensin receptor blockers, low-dose furosemide is prescribed. In the control group, only angiotensin receptor blocking drugs will be prescribed

Main outcome variables

Prevalence of persistent hypertension in day 5 post partum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230722058884N1**

Registration date: **2023-11-30, 1402/09/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-30, 1402/09/09**

Update count: **0**

Registration date

2023-11-30, 1402/09/09

Registrant information

Name

Maliheh Fakehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5560 6034

Email address

maryam.fakehi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the clinical effects of a short-term course of

Oral Furosemide in postpartum period in patients with preeclampsia during pregnancy : A Randomized Controlled Trial

Public title

Effect of Oral Furosemide on patients with preeclampsia during pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who have had a recent pregnancy with preeclampsia

Exclusion criteria:

Age under 18 Patients with prior history of hypertension
Patients with renal disease Patients with history of congenital heart defects

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **118**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization protocol for this clinical trial is designed to ensure the unbiased allocation of participants into different treatment groups. Prior to the start of the trial, a computer-generated randomization list will be created by an independent statistician who is not involved in the recruitment or allocation process. Using this list, participants will be assigned to one of two treatment arms in a random manner. The randomization process will not be stratified The allocation sequence will be concealed from the researchers, participants, and study personnel until the intervention is assigned. This rigorous randomization process reduces the likelihood of selection bias, increases internal validity, and allows for a more accurate assessment of the treatment effects in the subsequent analysis.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study only the patients will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University if Medical Sciences

Street address

Beside Milad Tower, Hemmat highway,

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2022-07-13, 1401/04/22

Ethics committee reference number

IR.IUMS.FMD.REC.1401.224

Health conditions studied

1

Description of health condition studied

Unspecified pre-eclampsia

ICD-10 code

O14.9

ICD-10 code description

Unspecified pre-eclampsia

Primary outcomes

1

Description

Prevalence of persistent hypertension in day 5 post partum

Timepoint

Day 5 post partum

Method of measurement

Manual sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with preeclampsia who are treated with ARB plus low does Furosemide

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi Hospital

Full name of responsible person

Parisa Hajari

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Beside Molavi Subway Station, Molavi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Mousavizadeh

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Parisa Hajari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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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