Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of enalapril versus amlodipine in controlling blood pressure in the postpartum period: a clinical trial study

Protocol summary

Study aim

Comparison of the Efficacy and Safety of Enalapril versus Amlodipine in Controlling Blood Pressure During the Postpartum Period

Design

A randomized, open-label, parallel-group, controlled Phase III clinical trial will be conducted on 120 patients. Using a block randomization method with block sizes of four, patients will be equally allocated into two groups.

Settings and conduct

This study will be conducted at Shahid Beheshti University of Medical Sciences-affiliated Mahdieh Hospital in Tehran, as well as hospitals in Qom and Kerman, over a three-month period in 2026–2027.

Participants/Inclusion and exclusion criteria

Age over 18 years and under 40 years Diagnosis of hypertension (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg) requiring initiation or adjustment of pharmacological treatment

Intervention groups

ntervention Group (Enalapril): Patients in this group will receive oral Enalapril at an initial dose of 5 mg once daily. If the target blood pressure (systolic blood pressure <140 mmHg and diastolic blood pressure <90 mmHg) is not achieved after 24 to 48 hours, and the medication is well tolerated, the Enalapril dose will be increased to 10 mg once daily. If necessary, the dose may be adjusted according to the protocol up to a maximum of 20 mg once daily (or 10 mg every 12 hours). Control Group (Amlodipine): Patients in this group will receive oral Amlodipine at an initial dose of 5 mg once daily. If the target blood pressure (systolic blood pressure <140 mmHg and diastolic blood pressure <90 mmHg) is not achieved after 24 to 48 hours, and the medication is well tolerated, the Amlodipine dose will be increased to 10 mg once daily.

Main outcome variables

Mean reduction in systolic blood pressure Mean reduction in diastolic blood pressure Time to achieve sustained blood pressure control Need for rescue medication with Labetalol Incidence of adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260522069482N1**
Registration date: **2026-10-29, 1405/08/07**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-29, 1405/08/07**
Update count: **0**

Registration date

2026-10-29, 1405/08/07

Registrant information

Name

Maryam Varzeshnejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2296 3164

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of enalapril versus amlodipine in controlling blood pressure in the postpartum period: a clinical trial study

Public title
Effectiveness of Enalapril Compared with Amlodipine in Controlling Blood Pressure During the Postpartum Period

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of hypertension (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg) requiring initiation or adjustment of pharmacological treatment.
Informed consent for participation in the study

Exclusion criteria:
History of hypersensitivity to the study medications (Enalapril or Amlodipine)

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Block After screening eligible patients and obtaining written informed consent, participants will be randomly allocated to two groups: the enalapril group and the amlodipine group. Block randomization with blocks of four will be used to generate the random allocation sequence. Each block will contain two allocations to the enalapril group and two allocations to the amlodipine group, with the order of these allocations determined randomly using random number generation software. The resulting allocation sequence will be placed in opaque, sealed, sequentially numbered envelopes. After each eligible patient enters the study, the corresponding envelope will be opened by the person responsible for allocation, and the patient will be assigned to one of the two groups according to the allocation specified in the envelope. Thus, participants will be randomly allocated to the two groups while maintaining a balanced number of participants in each group throughout the allocation process.

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
The Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
“Shoosh Square – Fadaeian Eslam Street, Shishehgar Khaneh Street, Rajabnia Street

City
Tehran

Province
Tehran

Postal code
1185817311

Approval date
2026-02-01, 1404/11/12

Ethics committee reference number
IR.SBMU.RETECH.REC.1405.093

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
010

ICD-10 code description
Pre-existing hypertension complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Mean reduction in systolic blood pressure

Timepoint
Measurements will be performed at predefined time points, including baseline (before the first dose of the medication) and subsequently at 2, 4, 8, 12, 24, 48, and 72 hours after treatment initiation.

Method of measurement
A calibrated digital blood pressure monitor

2

Description
Mean reduction in diastolic blood pressure

Timepoint
Measurements will be performed at predefined time points, including baseline (before the first dose of the medication) and at 2, 4, 8, 12, 24, 48, and 72 hours after treatment initiation.

Method of measurement

A calibrated digital blood pressure monitor

Secondary outcomes

1

Description
Need for rescue labetalo
Timepoint
Blood pressure will be measured at predefined time points, including baseline (before the first dose of the medication) and subsequently at 2, 4, 8, 12, 24, 48, and 72 hours after treatment initiation.
Method of measurement
A calibrated digital blood pressure monitor

2

Description
Readmission to hospital
Timepoint
Patients will be followed up on days 3, 7, and 10 after discharge to document hospital readmission.
Method of measurement
Patients will be followed up after discharge through review of electronic health records and telephone contact.

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive oral enalapril at an initial dose of 5 mg once daily. If the target blood pressure (systolic blood pressure <140 mmHg and diastolic blood pressure <90 mmHg) is not achieved after 24–48 hours, and the medication is well tolerated, the enalapril dose will be increased to 10 mg once daily. If necessary, the dose may be further titrated according to the study protocol to a maximum of 20 mg once daily (or 10 mg every 12 hours).
Category
Treatment - Drugs

2

Description
Control group:Patients in the control group will receive oral amlodipine at an initial dose of 5 mg once daily. If the target blood pressure (systolic blood pressure <140 mmHg and diastolic blood pressure <90 mmHg) is not achieved after 24–48 hours, and the medication is well tolerated, the amlodipine dose will be increased to 10 mg once daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdiyeh hospital
Full name of responsible person
Kimia Motevalian
Street address
Mahdiyeh Hospital, Rajab Nia St., Shishgarkhaneh St., Fedaiyan-e Eslam St., Shush Sq., Tehran, Iran
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Web page address
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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
7th Floor, Building No. 2, Shahid Beheshti University of Medical Sciences (SBMU), Arabi Ave., Daneshjoo Blvd., Velenjak, Tehran, Iran
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Postal code
1985717443
Phone
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Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research Deputy of 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
Kimia Motevalian
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Mahdiyeh Hospital, Rajab Nia St., Shishgarkhaneh St., Fedaiyan-e Eslam St., Shush Sq., Tehran, Iran
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Person responsible for scientific inquiries

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Position
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Latest degree
Specialist
Other areas of specialty/work
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Street address
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Person responsible for updating data

Contact
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Position
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mahdiyeh_hospital@sbmu.ac.ir

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
Yes - There is a plan to make this available
Title and more details about the data/document
Non-personally identifiable data and research-related documentation will be used solely for scientific, educational, and research purposes.
When the data will become available and for how long
Access period starts 6 months after results are published.
To whom data/document is available
Access to these data will only be possible for researchers, faculty members, graduate students, and other qualified individuals who submit a written request along with a description of the research purpose, data analysis method, and research ethics approval.
Under which criteria data/document could be used
The data provided may only be used for scientific analyses consistent with the approved research objectives, including secondary statistical analyses, systematic reviews, meta-analyses, and other relevant research. The data may not be used for any attempt to identify individuals, transfer data to third parties without permission, commercial use, or any use contrary to research ethics.

From where data/document is obtainable

Applicants seeking data or documentation for this study can first contact Dr. Kimia Motevalian, a physician at Mahdieh Hospital, Tehran, via email or the principal investigator's contact number. If necessary, correspondence can also be conducted through Mahdieh Hospital in Tehran. Requests will be addressed after review and in compliance with the principles of confidentiality, ethical considerations, and data-sharing regulations.

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

The applicant must submit a formal request to the lead investigator or the relevant committee. The request should include the purpose of the data use, the proposed analysis method, the applicant’s institutional affiliation, and the plan for publishing the results. The requests will be reviewed by the research team or data monitoring committee for compliance with scientific objectives, ethical considerations, and confidentiality requirements. If approved, the anonymized data will be made available to the applicant via a secure method after signing a Data Use Agreement

Comments