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Comparing intravenous labetalol and nicardipine for controlling severe high blood pressure in pregnant women with severe preeclampsia

Submission date
14/09/2026

Recruitment status
No longer recruiting

Registration date
16/09/2026

Overall study status
Completed

Last Edited
14/09/2026

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Severe preeclampsia is a serious pregnancy complication involving dangerously high blood pressure. Without prompt treatment, it can cause severe complications for the mother and baby. Intravenous labetalol and nicardipine are medicines used to lower blood pressure rapidly, but evidence directly comparing them in women with severe preeclampsia remains limited. This study aimed to compare how quickly and safely intravenous labetalol and intravenous nicardipine controlled severe high blood pressure.

Who can participate?
Pregnant women aged 18–50 years, at 20 weeks of pregnancy or later, who were diagnosed with severe preeclampsia and had a systolic blood pressure of at least 160 mmHg and/or a diastolic blood pressure of at least 110 mmHg could participate.

What does the study involve?
Participants were randomly assigned to receive either intravenous labetalol or intravenous nicardipine. Both medicines were administered by intravenous infusion, with the dose adjusted according to the participant's blood pressure response. The main measurement was the time required to achieve the target blood pressure. Researchers also assessed whether dose escalation was required, whether severe hypertension returned after the target blood pressure had been achieved, whether blood pressure control was sustained during six hours of monitoring, and whether maternal or fetal adverse effects occurred.

What are the possible benefits and risks of participating?
Both treatments were intended to achieve rapid and controlled blood pressure reduction and reduce the risk of complications caused by severe hypertension. Participants might not have received a direct additional benefit beyond the clinical treatment provided. Possible side effects included low blood pressure, changes in heart rate, headache, dizziness, nausea, vomiting, and fetal heart-rate changes. Participants were monitored closely during treatment.

Where is the study run from?
The study was coordinated by the Faculty of Medicine, Universitas Padjadjaran, and Dr. Hasan Sadikin General Hospital in Bandung, Indonesia. Recruitment was conducted at ten hospitals in West Java, Indonesia.

When did the study start and how long did it run?
The first participant was enrolled in September 2025, the final participant was enrolled in February 2026, and final outcome data collection was completed in March 2026.

Who funded the study?
The study was self-funded by the researchers and supported by academic resources from the Faculty of Medicine, Universitas Padjadjaran, and Dr. Hasan Sadikin General Hospital. No external commercial funding was received.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

ResearchRegistry UIN
researchregistry11781

Study information

Scientific Title
Sustained blood pressure control and rebound hypertension after acute antihypertensive therapy for severe preeclampsia: A multicenter randomized trial of intravenous labetalol versus nicardipine

Study objectives
To compare the effectiveness and short-term maternal and fetal safety of intravenous labetalol versus intravenous nicardipine for acute blood pressure control in pregnant women with severe preeclampsia. The primary objective was to compare the time required to achieve the target blood pressure. Secondary objectives included comparing dose-response patterns, rebound hypertension, sustained blood pressure control, and adverse events.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/08/2025, Research Ethics Committee of Dr. Hasan Sadikin General Hospital Bandung (Jl. Pasteur No. 38, Bandung, 40161, Indonesia; +62 22 2034953; a@a), ref: DP.04.03/D.XIV.6.5/395/2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Severe preeclampsia requiring acute intravenous antihypertensive treatment.

Interventions
Eligible participants were randomly assigned in a 1:1 ratio to receive intravenous labetalol or intravenous nicardipine in two parallel treatment groups. The random sequence was generated by an independent statistician using permuted block randomization with a block size of six. Allocation was concealed using sequentially numbered, opaque, sealed envelopes opened after confirmation of eligibility and written informed consent. Treating clinicians were not blinded because the treatments differed in preparation and administration, while the trained outcome assessor was blinded to treatment allocation.

Intervention group: Intravenous labetalol was administered by continuous infusion at an initial rate of 1–2 mg/min and titrated according to blood pressure response, up to a maximum total dose of 300 mg within 24 hours. Labetalol 25 mg/5 mL was diluted in 20 mL of 0.9% sodium chloride.

Active comparator group: Intravenous nicardipine was administered by continuous infusion at an initial rate of 5 mg/hour. The dose was increased by 5 mg/hour every 5 minutes according to blood pressure response, up to a maximum rate of 15 mg/hour. One 10-mL ampoule containing nicardipine 1 mg/mL was diluted in 90 mL of 0.9% sodium chloride.

Blood pressure was monitored during treatment and for six hours after the target blood pressure was achieved. The target was defined as a controlled reduction in mean arterial pressure not exceeding 20% or achievement of blood pressure at or below 140/90 mmHg.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Labetalol, nicardipine

Primary outcome(s)
1. Time to target blood pressure, defined as a controlled reduction in mean arterial pressure not exceeding 20% or achievement of blood pressure ≤140/90 mmHg, measured using routine clinical blood pressure monitoring time in minutes at the initiation of the assigned intravenous antihypertensive infusion until the target blood pressure was first achieved

Key secondary outcome(s)
1. Dose escalation requirement, recorded as the number and proportion of participants requiring dose escalation measured using routine clinical blood pressure monitoring at the initiation of the assigned intravenous antihypertensive infusion until the target blood pressure was first achieved

2. Rebound hypertension, defined as the recurrence of systolic blood pressure ≥160 mmHg and /or diastolic blood pressure ≥110 mmHg after the target blood pressure was initially achieved, measured using routine clinical blood pressure monitoring at the six-hour monitoring period after the target blood pressure was first achieved

3. Sustained blood pressure control, defined as the maintenance of blood pressure below the severe-hypertension threshold without additional rescue antihypertensive treatment, measured using routine clinical blood pressure monitoring at the six-hour monitoring period after the target blood pressure was first achieved

4. Maternal adverse events, including hypotension, bradycardia, tachycardia, headache, dizziness, nausea, and vomiting, measured using recorded through clinical observation and routine monitoring, at the initiation of the assigned treatment until completion of the six-hour monitoring period after achievement of the target blood pressure

5. Fetal adverse events measured using routine fetal heart-rate monitoring at the initiation of the assigned treatment until completion of the six-hour monitoring period after achievement of the target blood pressure

Completion date

31/03/2026

Eligibility

Key inclusion criteria
1. Pregnant women aged 18 years or older
2. Gestational age of 20 weeks or more
3. Diagnosed with severe preeclampsia according to the American College of Obstetricians and Gynecologists 2020 criteria
4. Systolic blood pressure of at least 160 mmHg and/or diastolic blood pressure of at least 110 mmHg
5. Treated in an emergency department, labour and delivery unit, or obstetric high-care unit at one of the participating hospitals

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
96

Key exclusion criteria
1. Asthma
2. Cardiac disease, including heart failure or atrioventricular block
3. Bradycardia
4. Known contraindication or allergy to intravenous labetalol or nicardipine
5. Incomplete clinical or outcome data
6. Twin or multiple pregnancy
7. Fetal congenital anomaly

Date of first enrolment
01/09/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment

Indonesia

Sponsor information

Organisation
Padjadjaran University

ROR
https://ror.org/00xqf8t64

Funder(s)

Funder type

Funder Name
Universitas Padjadjaran

Alternative Name(s)
Padjadjaran University, UNPAD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Indonesia

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data underlying the reported results may be made available after publication upon reasonable written request to the corresponding author, Dr Aditya Wibowo, aditya24011@mail.unpad.ac.id. Requests must include a scientifically valid research proposal and will be reviewed by the study investigators and relevant institutional authorities. Data will be shared only for approved research purposes, subject to ethical, legal, institutional, and participant-confidentiality requirements. Approved data will be transferred through a secure method. The availability period will follow the applicable institutional data-retention policy.

IPD sharing plan summary
Available on request