Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of bolus norepinephrine and phenylephrine for prophylaxis against post spinal anesthesia hypotension during elective caesarean delivery: A randomized controlled trial

Protocol summary

Study aim
This study aims to determine the effect of epinephrine on the control of vital signs during caesarean section using the neuraxial method will be done.

Design
The participants are pregnant women, 36 to 41 weeks, between 18 and 45 years old. The subjects in this study are divided into two groups, phenylephrine (PE) and norepinephrine (NEP), by random block method. The proposed sample size is 45 people in each group.(Phase 2 of the clinical trial)

Settings and conduct
Pregnant women between 36 and 41 weeks, between 18 and 45 years of age who referred to Sayad Shirazi Hospital in Gorgan for elective caesarean section during 2022

Participants/Inclusion and exclusion criteria
Inclusion criteria: candidates for elective cesarean section and do not have restrictions for spinal anesthesia, such as patient's lack of consent, sensitivity to anesthesia, injection site infection, and high intracerebral pressure. Exclusion Patients with uncontrolled cardiac complications, high blood pressure disorders in pregnancy, diabetes, psychiatric and kidney problems, systolic blood pressure less than 90 mmHg, peripheral bleeding, coagulation disorders are excluded from the study. Also, patients who have failed spinal anesthesia, sensory level higher than T5, unpredictable complications during surgery, such as bleeding during surgery more than normal have a cesarean section without problems (more than 1500 ml). are excluded from the study.

Intervention groups
Immediately after spinal anesthesia, phenylephrine is injected at a dose of 50 µg/ml for the first group and norepinephrine at a dose of 5 µg/ml for the second group.

Main outcome variables
Blood pressure; heart rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20080921001264N13**
Registration date: **2023-01-31, 1401/11/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-31, 1401/11/11**
Update count: **0**

Registration date
2023-01-31, 1401/11/11

Registrant information

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-21, 1401/02/01
Expected recruitment end date
2023-02-20, 1401/12/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of bolus norepinephrine and phenylephrine for prophylaxis against post spinal anesthesia hypotension during elective caesarean delivery: A randomized controlled trial

Public title
The effect of bolus injection of phenylephrine and norepinephrine in preventing hypotension after spinal anesthesia in patients undergoing elective cesarean elective.
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
The participants in this study include pregnant women, 36 to 41 weeks, between 18 and 45 years old, who referred to Sayad Shirazi Hospital in Gorgan. These patients are candidates for elective Cesarean elective Do not have any restrictions for spinal anesthesia such as patient's lack of consent, sensitivity to anesthesia, injection site infection, and high intracerebral pressure. Patients who enter the study in case of failure of spinal anesthesia, unpredictable complications during surgery, such as bleeding during surgery more than normal for a cesarean section without problems (more than 1500 ml) and the sensory level of T4 is higher than are excluded from the study.
Exclusion criteria:
At the beginning of the study, patients with uncontrolled heart complications, high blood pressure disorders in pregnancy, diabetes, psychiatric and renal problems, systolic blood pressure less than 90 mm Hg, peripheral bleeding, coagulation disorders
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features
The study is designed in a random manner and after approval by the ethics committee of the university and registration in the clinical studies system of Iran, the consent form is fully explained to all pregnant women who are part of the study criteria. By meeting the existing conditions and understanding the informed consent, consent to conduct the study is obtained from them.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in biomedical research of the Gorgan University of Medical Sciences
Street address
3rd floor- Shahid Dr. Abdullah Abbasi Heart Superspeciality Center- Shahid Sayad Shirazi Hospital- Gorgan
City
Gorgan
Province
Golestan
Postal code
4917867439
Approval date
2021-11-14, 1400/08/23
Ethics committee reference number
IR.GOUMS.REC.1400.374

Health conditions studied

1

Description of health condition studied
Complications of anesthesia during the puerperium
ICD-10 code
O89
ICD-10 code description
Complications of anesthesia during the puerperium

Primary outcomes

1

Description
In the first few minutes after the injection of both drugs, we expect an increase in blood pressure, and we also expect to maintain the heart rate after the use of norepinephrine.
Timepoint
It was monitored every 2 minutes to 6 minutes, every 3 minutes to 15 minutes and every 5 minutes until the end of the surgery.
Method of measurement
An increase in blood pressure was calculated as an increase in systolic pressure greater than 120% of baseline and a drop in blood pressure was calculated

based on a decrease in systolic blood pressure below 80% of baseline.

Secondary outcomes

1

Description
Due to the short half-life of the drug, which is up to 3 minutes, and its metabolite is also inactive, we do not expect secondary effects.
Timepoint
5 minutes later
Method of measurement
In this study, an increase in blood pressure is calculated as an increase in systolic pressure more than 120% of the baseline, and a drop in blood pressure is calculated based on a decrease in systolic blood pressure below 80% of the baseline.

Intervention groups

1

Description
Intervention group: NE norepinephrine group: 45 people: these people receive NE with a dose of 5 micrograms.
Category
Treatment - Drugs

2

Description
Control group: Phenylephrine PE group: 45 people: these people receive PE at a dose of 50 micrograms.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sayad Shirazi Educational and Medical hospital in Gorgan city
Full name of responsible person
Dr. Erazbardi Ghorchaei
Street address
3rd floor- Shahid Dr. Abdullah Abbasi Heart Superspeciality Center- Shahid Sayad Shirazi Hospital- Gorgan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
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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
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Erazbardi Ghorchaei
Position
Associate professor
Latest degree
Specialist
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
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Our data will be available only to researchers working in academic and scientific institutions, and also people who work in industry can apply to receive them.
Under which criteria data/document could be used
To promote science
From where data/document is obtainable
Dr. Saideh Yazdanpanah sepideh.yp.md@gmail.com Dr. Sima Basharat sbesharatgp@gmail.com Dr. Erazberdi Ghourchaei arazberdi@gmail.com
What processes are involved for a request to access data/document
After sending an e-mail and a comprehensive explanation about the reason for using the data files, and after consulting with the rest of the project members, the data will be provided within 15 days.
Comments