Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the Effect of Phenylephrine Prophylactic Infusion with Placebo Group on Hypertension and Nausea and Vomiting of Pregnant Women During Cesarean Section Under Spinal Anesthesia

Protocol summary

Study aim
Determination of the Effect of Phenylephrine Infusion on Maternal Hemodynamic Changes during Spinal Anesthesia for Cesarean Delivery

Design
A randomized, placebo-controlled, parallel, double-blind clinical trial , 116 samples, phase 3

Settings and conduct
This study was a double-blind randomized controlled trial that conducted on 116 pregnant women candidate for elective cesarean section by spinal anesthesia in Shahid Akbarabadi hospital (Tehran) in 2019

Participants/Inclusion and exclusion criteria
Inclusion criteria: pregnant woman 18-45 years, candidate for cesarean section by spinal anesthesia, ASA1 & 2 and elective cesarean section. exclusion criteria: a history of allergy to phenylephrine, BMI>30 Kg/M2, hypertension (>140/90 mmHg), contraindication for spinal anesthesia, severe cardiovascular disease, prematurity, emergency cesarean section and inadequate analgesia after spinal anesthesia.

Intervention groups
In the intervention group, 35 µg / kg phenylephrine was injected. Spinal anesthesia was performed with 12 mg bupivacaine 0.6% in a sitting position in the L3-L4 or L5-L4 space using the G25 spinal needle. After anesthesia, the patient was placed in the retina position with a slight displacement of the uterus to prevent uterine pressure on the aorta and vena cows. By the time of the baby's birth, blood pressure is measured every two minutes.

Main outcome variables
systolic blood pressure, diastolic blood pressure, heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191007045023N1**
Registration date: **2019-11-08, 1398/08/17**
Registration timing: **retrospective**

Last update: **2019-11-08, 1398/08/17**
Update count: **0**

Registration date
2019-11-08, 1398/08/17

Registrant information

Name
Amineh Shafei nia

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2635 2805

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-01, 1397/10/11

Expected recruitment end date
2019-08-30, 1398/06/08

Actual recruitment start date
2019-01-01, 1397/10/11

Actual recruitment end date
2019-08-30, 1398/06/08

Trial completion date
2019-09-30, 1398/07/08

Scientific title
Comparison of the Effect of Phenylephrine Prophylactic

Infusion with Placebo Group on Hypertension and Nausea and Vomiting of Pregnant Women During Cesarean Section Under Spinal Anesthesia

Public title
The effect of phenylephrine on blood pressure and nausea and vomiting in pregnant women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women 18-45 years Pregnant women candidates for cesarean section by spinal anesthesia ASA Class 1 and 2 Elective cesarean section
Exclusion criteria:
history of allergy to phenylephrine BMI>30 Kg/M2 hypertension (>140/90 mmHg) contraindication for spinal anesthesia severe cardiovascular disease prematurity emergency cesarean section inadequate analgesia after spinal anesthesia
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **120**
Actual sample size reached: **116**
Randomization (investigator's opinion)
Randomized
Randomization description
A quadratic permutation block method was used. Subjects in blocks 1, 3 and 5 entered into the control group and subjects in blocks 2, 4 and 6 entered into the intervention group and simple randomized table was used to select blocks. The random assignment sheet will be used by trained personnel to assign patients to study groups (Concealment).
Blinding (investigator's opinion)
Double blinded
Blinding description
The placebo was similar to the drug regarding shape of syringe, color, and volume and the researcher and patient were not aware of the type of injection or placebo. The outcome assessor did not know the types of the patient's intervention and only had the patient's specific code.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Next to Milad Tower, Hemat Highway ,Tehran
City
Tehran
Province
Tehran
Postal code
14496-14535
Approval date
2018-03-05, 1396/12/14
Ethics committee reference number
IR.IUMS.REC.1397.868

Health conditions studied

1

Description of health condition studied
Pregnancy
ICD-10 code
O10
ICD-10 code description
Pre-existing hypertension complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
systolic blood pressure
Timepoint
every two minutes
Method of measurement
sphygmomanometer

2

Description
diastolic blood pressure
Timepoint
every two minutes
Method of measurement
sphygmomanometer

3

Description
heart rate
Timepoint
every two minutes
Method of measurement
puls oxymetrie

Secondary outcomes

1

Description
Arterial pressure
Timepoint
Every two minutes
Method of measurement
Sphygmomanometer

2

Description
SPO2
Timepoint
Every two minutes
Method of measurement
Pulse oximetry

3

Description
Nausea
Timepoint
One time, imminently after delivery
Method of measurement
Observing

4

Description
PH
Timepoint
One time, imminently after delivery
Method of measurement
Blood sample

5

Description
PCO2
Timepoint
One time, imminently after delivery
Method of measurement
Blood sample

6

Description
HCO3
Timepoint
One time, imminently after delivery
Method of measurement
Blood sample

7

Description
Apgar 1
Timepoint
One time, imminently after delivery
Method of measurement
Observing

8

Description
Apgar 5
Timepoint
One time, imminently after delivery
Method of measurement
Observing

Intervention groups

1

Description
Intervention group: In the intervention group, 35 µg / kg phenylephrine was injected. Spinal anesthesia was performed with 12 mg bupivacaine 0.6% in a sitting position in the L3-L4 or L5-L4 space using the G25 spinal needle. After anesthesia, the patient was placed in the retina position with a slight displacement of the uterus to prevent uterine pressure on the aorta and vena cows. By the time of the baby's birth, blood pressure is measured every two minutes.
Category
Treatment - Drugs

2

Description
Control group: 0.9% normal saline serum was injected. Then spinal anesthesia was performed with 12 mg Bupivacaine 0.5% in sitting position in space of L3-L4 or L5-L4 using spinal needle G25.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbarabadi hospital
Full name of responsible person
Amineh Shafei nia
Street address
Molavi street, Molavi intersection, Ferdowsi garden station
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Sponsors / Funding sources

1

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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
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
Amineh Shafei nia
Position
Assistant Professor of Anesthesiology
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
The data will be available one month after the responsible person's approval

When the data will become available and for how long
The access period will start from 2019 to 2021

To whom data/document is available
Data will be available to researchers working in the university.

Under which criteria data/document could be used
Just for performing research

From where data/document is obtainable
Refer to the responsible person for accessing the data

What processes are involved for a request to access data/document
The data will be available one month after the responsible person's approval

Comments