Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Phenylephrine and Ephedrine in treatment of Spinal Anesthesia induced Hypotension in pregnant women candidate for Cesarean section

Protocol summary

Study aim

Determine the effects of Phenylephrine and Ephedrine in the treatment of spinal anesthesia induced Hypotension in pregnant women undergoing Cesarean section

Design

Two groups of parallel, clinical trial, double blinded

Settings and conduct

In this study, 62 patients undergoing elective cesarean section under spinal anesthesia and having hypotension after spinal anesthesia are examined. Patients are randomized to either Phenylephrine or Ephedrine. Patients receive an intravenous intravenous bolus of 100 microgram Phenylephrine or 10 milligram Ephedrine immediately after hypotension after spinal anesthesia. During surgery (during spinal anesthesia, at the outlet of the infant and up to the end of the operation) hemodynamic variables including systolic, diastolic blood pressure and heart rate were measured every 5 minutes. After the removal of the baby, the umbilical cord blood gases were analyzed and Apgar The baby is recorded in minutes 1 and 5. The Apgar score is calculated by the physician, which is not related to the type of drug used

Participants/Inclusion and exclusion criteria

The criteria for healthy pregnant women with uncomplicated singleton class ASA 1 between the ages of 20 to 35 years is higher than 36 weeks' gestation for elective cesarean section under spinal anesthesia. Exit criteria include: Emergency cesarean section, high risk pregnancies, and any contraindication for spinal anesthesia.

Intervention groups

In this study, pregnant women with Cesarean section under spinal anesthesia were randomly divided into two groups to find the best medicine for improving hypotension due to spinal anesthesia with the least effect on Apgar score and neonatal PH.

Main outcome variables

Find the best medicine to improve blood pressure in pregnant women undergoing cesarean section under spinal anesthesia with minimal effect on the Apgar score and neonatal PH

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024909N8**
Registration date: **2019-06-16, 1398/03/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-16, 1398/03/26**
Update count: **0**

Registration date

2019-06-16, 1398/03/26

Registrant information

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Faranak Rokhtabnak
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Phenylephrine and Ephedrine in treatment of Spinal Anesthesia induced Hypotension in pregnant women candidate for Cesarean section

Public title
"Effect of Phenylephrine in treatment of Hypotension"; "Effect of Ephedrine in treatment of Hypotension"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Higher than 36 weeks of gestational age Elective cesarean section under spinal anesthesia Pregnant women are healthy and uncomplicated with class ASA 1
Exclusion criteria:
Emergency Caesarean section High-risk pregnancies Spinal anesthesia is contraindicated
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, before the patient enters the operating room on the basis of a self-contained envelope, one of the two envelopes in which the type of blood pressure enhancer is written is randomly selected.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, before entering the patient into the operating room on the basis of an envelope, one of the two envelopes containing the type of blood pressure enhancer was randomly selected and the medicine was given to the treatment staff. It is calculated at the time of the birth of the Apgar's baby by a physician who does not know about the type of prescription drug.
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 of Medical Sciences
Street address
Firoozgar Hospital, Beh Afarin St., Karim Khan St., Valiasr Square
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Postal code
1593747811
Approval date
2017-11-13, 1396/08/22
Ethics committee reference number
IR.IUMS.FMD.REC 1396.9411174004

Health conditions studied

1

Description of health condition studied
Decreased blood pressure following spinal anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood pressure
Timepoint
Mean 3 times the blood pressure measurement before the procedure and then measuring the blood pressure at intervals of 3 minutes after the spinal anesthesia until the birth of the baby, and then every 5 minutes
Method of measurement
Automatic non-invasive blood pressure measurement device

2

Description
Heart rate
Timepoint
It is instantaneously observed and recorded simultaneously with blood pressure recordings.
Method of measurement
Based on the electrocardiographs attached to the patient and observed on the monitor

Secondary outcomes

1

Description
PH newborn
Timepoint
Maximum in one minute after leaving the uterus
Method of measurement
Blood gas analyzer

2

Description
Baby Apgar score
Timepoint
In the 1st and 5th minutes of birth
Method of measurement
Based on Apgar Score Table

Intervention groups

1

Description
First intervention group: Phenylephrine receiving 100 microgram Bolus. Repeat this dose if needed.
Category
Treatment - Drugs

2

Description
Second Intervention group: Ephedrine receiving 10 milligram bolous. Repeat this dose if needed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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Position
Associate professor
Latest degree
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
The whole potential data is unpublished after being unidentifiable
When the data will become available and for how long
Start the access period after printing the results
To whom data/document is available
All researchers
Under which criteria data/document could be used
For use to complete and upgrade similar topics
From where data/document is obtainable
Send request to email rkhtbnk@yahoo.com
What processes are involved for a request to access data/document
After reviewing the request and if you have reasonable cause data will be placed at their disposal.
Comments