Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Norepinephrin and Ephedrine in the treatment of hypotension due to spinal anesthesia in cesarean section on fetal umbilical cord pH - A double-blinded randomized controlled trial

Protocol summary

Study aim

Comparison of the effect of norepinephrine and ephedrine in the treatment of hypotension induced by spinal anesthesia in cesarean section on fetal umbilical cord artery pH and lactate

Design

This study will be conducted as a double-blind randomized phase 3 clinical trial in two groups with 48 participants who are treated with Ephedrine or Norepinephrine. Randomization will be done by Randomization Allocation Software.

Settings and conduct

This study will be conducted in Akbarabadi Hospital in 1401. Patients will be blinded to type of injected medicine. Only the anesthesiologist will be aware of patient allocation and will control the condition of the patients during anesthesia. Outcomes will be collected in checklists by one of the researchers who is not aware of the patients' allocation.

Participants/Inclusion and exclusion criteria

The inclusion criteria is pregnant women between 36 to 40 weeks of gestational age with singleton pregnancy who are chosen for elective cesarean section. Pregnant women between 20 and 35 years old will be selected for study. Patients with history of hypertension (>140/90), cardiovascular or cerebrovascular diseases, complications of pregnancy such as gestational hypertension, high-risk pregnancies (e.g. multiparity and intrauterine growth retardation), abnormality of placenta and umbilical cord will be excluded. Contraindications to spinal anesthesia e.g. patient's refusal for spinal anesthesia, blood coagulopathies, infection in the anesthesia area, bleeding or hypovolemic shock are other exclusion criteria.

Intervention groups

In each group, in case of hypotension (drop in systolic blood pressure more than 20% of the patient's baseline blood pressure), ephedrine bolus 10 mg or norepinephrine bolus 10 µg is injected.

Main outcome variables

Umbilical artery pH level, Umbilical artery lactate level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160529028141N4**
Registration date: **2022-10-29, 1401/08/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-29, 1401/08/07**
Update count: **0**

Registration date

2022-10-29, 1401/08/07

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-03-20, 1401/12/29

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

Scientific title
Comparison of the effect of Norepinephrin and Ephedrine in the treatment of hypotension due to spinal anesthesia in cesarean section on fetal umbilical cord pH - A double-blinded randomized controlled trial

Public title
Comparison of the effect of Norepinephrin and Ephedrine in the treatment of hypotension due to spinal anesthesia in cesarean section on fetal umbilical cord PH
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women Age 20 to 35 years Candidate for elective cesarean section Singleton pregnancy Gestational age 36 to 40 weeks
Exclusion criteria:
History of hypertension (>140/90) History of cardiovascular or cerebrovascular diseases Gestational hypertension History of high-risk pregnancies (e.g. multiparity or intrauterine growth retardation) Abnormalities of the placenta and umbilical cord Contraindications to spinal anesthesia (patient refusal for spinal anesthesia, coagulopathies, infection in the anesthesia area, bleeding or hypovolemic shock)
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization with different block sizes will be used to randomly assign two groups with 24 participants in each group (48 patients in total). The size of the blocks will be a multiple of 2 and a divisor of 48. Initially, the block sizes are chosen randomly. Then, for each block, different permutations are randomly determined by the Randomization Allocation Software. In each block, the number of patients in the groups is equal, and blinding is used to not reveal the permutations in the last patients of each block.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is conducted in a double-blind manner. The patients will be blind to type of injected medicine. Only the anesthesiologist will be aware of patient allocation and will control the condition of the patients during anesthesia. Outcomes will be collected in checklists by one of the researchers who is not aware of the patients' allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of medicine - Iran university of medical sciences (Research Ethics Committee)
Street address
Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2022-08-06, 1401/05/15
Ethics committee reference number
IR.IUMS.FMD.REC.1401.262

Health conditions studied

1

Description of health condition studied
Hypotension induced by spinal anesthesia in cesarean section
ICD-10 code
O74.6
ICD-10 code description
Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description
Umbilical artery pH level
Timepoint
Immediately after delivery
Method of measurement
Biochemical tests

2

Description
Umbilical artery lactate level
Timepoint
Immediately after delivery
Method of measurement
Biochemical tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: In case of hypotension induced by spinal anesthesia (drop in systolic blood pressure more than 20% of baseline), 10 milligram bolus norepinephrine will be injected.
Category
Treatment - Drugs

2

Description
Control: In case of hypotension induced by spinal anesthesia (drop in systolic blood pressure more than 20% of baseline), 10 milligram bolus ephedrine will be injected.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbarabadi educational and therapeutic center
Full name of responsible person
Ali Mazouri
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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
Ali Mazouri
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available