Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anaesthesia for caesarean section

Protocol summary

Study aim
Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anaesthesia for caesarean section.

Design
Women undergoing cesarean section under spinal anesthesia 18 to 35 years

Settings and conduct
This double-blind clinical trial study will be performed on 100 patients undergoing cesarean section in two groups at Mousavi Hospital in Zanjan. Random allocation of samples is done by block method and using statistical software. A digital sphygmomanometer will be used to measure blood pressure and heart rate. Completion of questionnaires and recording of variables will be done by the research team during the operation and at specified times.

Participants/Inclusion and exclusion criteria
Entry requirements: Patients who are candidates for elective cesarean section, full-term pregnancy (37 full weeks) and singleton, patients with American Society of Anesthesiologists (ASA) 1 and 2, no underlying diseases, no drug and alcohol abuse Exit conditions: Congenital malformations of the infant, patients who have had a previous cesarean section performed midline, patients who, for whatever reason, the time between spinal anesthesia and the discharge of the baby is longer than usual (20 Minutes), patients who have failed during spinal anesthesia

Intervention groups
Intervention group: Pregnant women with term pregnancies and aged 18 to 35 years who receive norepinephrine infusion (4µ g / min) immediately after spinal anesthesia until the end of cesarean section Control group: Pregnant women with term gestation and aged 18 to 35 years who receive phenylephrine infusion (4 mg / min) immediately after spinal anesthesia until the end of cesarean section

Main outcome variables
Systolic blood pressure; Diastolic blood pressure; Moderate blood pressure; heart ; Arterial umbilical cord blood gases

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210502051160N1**
Registration date: **2021-07-11, 1400/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-11, 1400/04/20**
Update count: **0**

Registration date
2021-07-11, 1400/04/20

Registrant information

Name
mitra hojatansari

Name of organization / entity

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Iran (Islamic Republic of)

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+98 24 3341 5118

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mitraansari@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-10, 1400/03/20

Expected recruitment end date
2021-12-11, 1400/09/20

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

Scientific title
Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anaesthesia for caesarean section

Public title
Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anaesthesia for caesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients candidate for cesarean section selectively Term pregnancy (37 full weeks) and singleton Patients with anesthesia class (ASA) 1 and 2 No abuse of drugs, drugs and alcohol
Exclusion criteria:
Congenital malformations of the neonate Patients in a position suspected of having a dead fetus Patients whose previous cesarean section is midline
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the restricted randomization method we use the block randomization type. Blocking is used to balance the number of samples assigned to each of the study groups. This feature helps the researcher to equate the number of samples assigned to each of the study groups whenever intermediate analyzes are needed during sampling. The size of all the blocks is equal and in this two-group experiment we will have 6 blocks (including 3 people in the intervention group and 3 people in the control group).software allocation Random is used for randomization. In addition to simple randomization, these softwares are able to generate random sequence by blocking method. For concealment, we use concealment allocation, which is the method used to execute a random sequence on the study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes with random sequences (envelopes opaque, sealed, numbered sequentially), each of the random sequences created is written on a card and the cards are placed inside the envelopes in order.In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed in a box, respectively. At the time of arrival of eligible pregnant mothers, according to the order of inclusion in the study, one of the envelopes is opened and the assigned group of the pregnant mother is revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drug will be inserted anonymously into the infusion syringe
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences
Street address
Vice-Chancellor for Research and Technology, 3th Floor, 2th Bldg., Zanjan University of Medical Sciences, Azadi Blvd. Zanjan, IRAN.
City
Zanjan
Province
Zanjan
Postal code
4515613191
Approval date
2021-04-27, 1400/02/07
Ethics committee reference number
IR.ZUMS.REC.1400.047

Health conditions studied

1

Description of health condition studied
hypotension during spinal anaesthesia
ICD-10 code
I95.81
ICD-10 code description
Postprocedural hypotension

Primary outcomes

1

Description
blood pressure
Timepoint
per one minute
Method of measurement
electronical pressure gauge

Secondary outcomes

empty

Intervention groups

1

Description
Patients in intervention group 1: After spinal anesthesia for cesarean section in pregnant women, intravenous infusion of norepinephrine 5 micrograms per minute up to a maximum of 60 ml per minute is started.Intervention group:
Category
Prevention

2

Description
Patients in intervention group 2: After spinal anesthesia for cesarean section in pregnant women, intravenous infusion of phenylephrine half a mg per minute to a maximum of 60 ml per minute is started.Intervention group:
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
saeid jalili
Street address
Ayatollah Mousavi Educational and Medical Center, Gavazang, Zanjan, IRAN.
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Alireza Shoghli
Street address
Vice-Chancellor for Research and Technology, 3th Floor, 2th Bldg., Zanjan University of Medical Sciences, Azadi Blvd. Zanjan, IRAN.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Saeed Jalili
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
There is no more information.
When the data will become available and for how long
There is no more information.
To whom data/document is available
There is no more information.
Under which criteria data/document could be used
There is no more information.
From where data/document is obtainable
There is no more information.
What processes are involved for a request to access data/document
There is no more information
Comments