Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the prophylactic infusion effect of Phenylephrine on hypotension in cesarean section under spinal anesthesia

Protocol summary

Study aim
Evaluation of the prophylactic infusion effect of phenylephrine on hypotension in cesarean section under spinal anesthesia

Design
In this double-blind clinical trial study, pregnant women candidates for cesarean section under spinal anesthesia were included. The patients were randomly allocated into intervention or control groups based on generated computer numbers.

Settings and conduct
This study was conducted on pregnant women undergoing cesarean section under spinal anesthesia admitted to Urmia Shahid Motahari. this study was a double-blind study and both of the patients and the researcher were blind to the belonging of the patients to the intervention or control group.

Participants/Inclusion and exclusion criteria
In this double-blind clinical trial study, pregnant women candidates for cesarean section under spinal anesthesia and ASA I and ASA II were included. Patients with classic hypertension or gestational hypertension, patients with pulmonary, cardiovascular, and cerebrovascular diseases, and also fetal abnormalities were excluded.

Intervention groups
The participants were randomly divided into two groups based on generated computer numbers. Patients in the intervention group received 100 micrograms per hour of Phenylephrine infusion. Patients in the control group received the same amount of normal saline.

Main outcome variables
Hypotension which was considered as a decrease in systolic blood pressure by 80% of the baseline; Hypertension was considered as an increase in systolic blood pressure above 120% of the baseline.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201207049639N1**
Registration date: **2020-12-20, 1399/09/30**
Registration timing: **retrospective**

Last update: **2020-12-20, 1399/09/30**
Update count: **0**

Registration date
2020-12-20, 1399/09/30

Registrant information

Name
Hadi Houshyar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 44 3346 9931

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hooshyar.h@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
2019-03-21, 1398/01/01

Actual recruitment end date
2020-03-19, 1398/12/29

Trial completion date
2020-03-19, 1398/12/29

Scientific title
Evaluation of the prophylactic infusion effect of Phenylephrine on hypotension in cesarean section under spinal anesthesia

Public title
Evaluation of the Phenylephrine effect on hypotension in cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women candidates for cesarean section under spinal anesthesia American Society of Anesthesiologists classification system I and II (ASA II and ASA II)
Exclusion criteria:
Patients with classical hypertension Gestational hypertension Patients with pulmonary and cardiovascular diseases Patients with cerebrovascular disease Fetal abnormality
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly divided into intervention and control groups using random allocation computer software. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients allocated into two groups according computer generated numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study was a double-blind clinical trial. participants and researcher were unaware about the patient belonged to the intervention or control groups. The drug were injected by an anesthesia technician (other than the researcher) who was unaware of the content of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Resalat Street, Jahad Ave., Urmia, Iran
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2019-01-16, 1397/10/26
Ethics committee reference number
IR.UMSU.REC.1397.408

Health conditions studied

1

Description of health condition studied
Hypotension
ICD-10 code
I95
ICD-10 code description
Hypotension

Primary outcomes

1

Description
Hypotension, which was considered as a decrease in systolic blood pressure by 80% of the baseline.
Timepoint
Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.
Method of measurement
Blood pressure monitoring device

Secondary outcomes

1

Description
Hypertension was considered as an increase in systolic blood pressure above 120% of the baseline
Timepoint
Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.
Method of measurement
Blood pressure monitoring device

2

Description
Nausea
Timepoint

Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.

Method of measurement

Interview

3

Description

Vomiting

Timepoint

Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.

Method of measurement

Interview

4

Description

Bradycardia (decrease in heart rate to less than 60 beats per minute)

Timepoint

Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.

Method of measurement

Heart rate monitoring device.

Intervention groups

1

Description

Intervention group: patients in the intervention group received 100 micrograms per hour of Phenylephrine infusion

Category

Treatment - Drugs

2

Description

Control group: patients in the control group received 100 micrograms of normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Motahari Hospital

Full name of responsible person

Dr. Hadi Hooshyar

Street address

Shahid Motahhari hospital; Kashani street, Urmia, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

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Urmia University of Medical Sciences; Resalat street; Jahad Blvd; Urmia; Iran.

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Hadi Hooshyar

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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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
Not applicable
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The results of the study will be published as an article.
When the data will become available and for how long
After publishing the article
To whom data/document is available
Researchers
Under which criteria data/document could be used
As published article
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
By email address of corresponding author
Comments