Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Effect of prophylactic infusion of phenylephrine on mothers' hemodynamic at Caesarean section with spinal anesthesia

Protocol summary

Summary

The present study aims to study the effects of prophylactic infusion of phenylephrine on mothers' hemodynamic at Caesarean section with spinal anesthesia. It is a single blind clinical study. 80 pregnant women attending Imam Reza hospital and Motazedi hospital requesting for elective ceasarean section were randomly selected and divided into experiment and control groups, each including 40 students. Data scope passport device , made in America, was used at the beginning of the study to monitor and record vital signs (such as systolic and diastolic blood pressure) non-invasive method, heart bit and oxygen saturation. In the experiment group, 12.5 milligram anesthetic bupivacaine hyperbaric 0.5 was injected intrathecally using 25-spinal needle in L4-L-5 environment and patients immediately were set in supine position. In the control group, Phenylephrine was not injected; in the case of hypotension, common treatment with ephedrine is used to control blood pressure. Immediately after intrathecal injection of the anesthetic, both experiment and control groups were measured and recorded for their vital signs every minute until their delivery, and, also, every three minutes to the end of the surgery by monitoring device. Inclusion: single pregnancy, BMI larger than 20and less than 35, over 36 weeks of pregnancy, patients at their 18 to 40, patients' satisfaction. Exclusion: coagulopathy or infection in spinal or any other contraindications to spine anesthesia, sensitivity to phynylephrine and bupivacaine, mothers' hypertension, cardiovascular diseases, cerebrovascular disease, congenital abnormalities of the fetus, diabetic mothers

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022414333N29**

Registration date: **2015-03-11, 1393/12/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-11, 1393/12/20

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

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Recruitment status

Recruitment complete

Funding source

kermanshah University of Medical Sciences

Expected recruitment start date

2014-06-05, 1393/03/15

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prophylactic infusion of phenylephrine on mothers' hemodynamic at Caesarean section with spinal anesthesia

Public title

Effect of prophylactic infusion of phenylephrine on mothers' hemodynamic at Caesarean section with spinal anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion: single pregnancy, BMI larger than 20and less than 35, over 36 weeks of pregnancy, patients at their 18 to 40, patients' satisfaction. Exclusion: coagulopathy or infection in spinal or any other contraindications to spine anesthesia, sensitivity to phynylephrine and bupivacaine, mothers' hypertension, cardiovascular diseases, cerebrovascular disease, congenital abnormalities of the fetus, diabetic mothers

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2014-01-14, 1392/10/24

Ethics committee reference number
420/7/1716/پ

Health conditions studied

1

Description of health condition studied
Spinal anesthesia

ICD-10 code
O29.5

ICD-10 code description
Other complications of spinal and epidural anaesthesia during pregnancy

Primary outcomes

1

Description
Mothers systolic blood pressure

Timepoint
Beginning to the study, every minute till the delivery and every three minutes to the end of the study

Method of measurement
By monitoring device

2

Description
Mothers diastolic blood pressure

Timepoint
Beginning to the study, every minute till the delivery and every three minutes to the end of the study

Method of measurement
By monitoring device

3

Description
Mothers heart bit

Timepoint
Beginning to the study, every minute till the delivery and every three minutes to the end of the study

Method of measurement
By monitoring device

4

Description
Oxygen saturation in mothers

Timepoint
Beginning to the study, every minute till the delivery and every three minutes to the end of the study

Method of measurement
By monitoring device

5

Description
Nausea and vomiting

Timepoint
Beginning to the study, every minute till the delivery and every three minutes to the end of the study

Method of measurement
Based on the observations by the doctor and asking the patients

6

Description
Infant apgar
Timepoint
1, 5 and 10 minutes after delivery
Method of measurement
Based on the observations by the doctor

7

Description
Sensory block level
Timepoint
1, 3, 5 and 30 minutes after spinal anesthesia
Method of measurement
Based on the observations by the doctor

8

Description
Mean arterial pressure
Timepoint
Beginning to the study, every minute till the delivery and every three minutes to the end of the study
Method of measurement
By monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
In the experiment group, 12.5 milligram anesthetic bupivacaine hyperbaric 0.5 was injected intrathecally using 25-spinal needle in L4-L-5 environment and patients immediately were set in supine position. Immediately after intrathecal injection of the anesthetic, mothers were measured and recorded for their vital signs every minute until their delivery, and, also, every three minutes to the end of the surgery by monitoring device.
Category
Treatment - Drugs

2

Description
In the control group, Phenylephrine was not injected; in the case of hypotension, common treatment with ephedrine is used to control blood pressure. Immediately after intrathecal injection of the anesthetic, mothers were measured and recorded for their vital signs every minute until their delivery, and, also, every three minutes to the end of the surgery by monitoring device.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emamreza Hospital
Full name of responsible person
Dr. Mahmood Kohansal
Street address
Emamreza hospital, Parastar boulevard
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Ali Karbasfrushan
Position

Anestisologist

Other areas of specialty/work

Street address

Emamreza hospital, Parastar boulevard

City

Kermanshah

Postal code

Phone

+98 83 3427 6309

Fax

Email

ali_karbasfrushan@yahoo.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty