

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 cesarean 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-L5 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 20 and 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)

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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 20 and 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 phenylephrine 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	
<u>1</u>	
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	

<u>1</u>	
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	
<u>1</u>	
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
<u>2</u>	
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
<u>3</u>	
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
<u>4</u>	
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
<u>5</u>	
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