

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### 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**

#### **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*