

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of two spinal anesthesia approaches: median and paramedian neuraxial blocks on PDPH for cesarean section operations

#### Protocol summary

##### Summary

Aim: Finding the technique, median or paramedian, with least prevalence of post dural puncture headache (PDPH). Design: One centered recruited parturients from Shariati hospital of Bandar Abbas .150 women entered the double -blind randomized (Blocks) study. Divided into two groups of 75 patients, (the median and paramedian groups). Recruitment has finished. Inclusion criteria: 15-45 years old, elective cesarean section. Exclusion criteria: ASA III-IV, more than one dural puncture, previous PDPH, contraindication for spinal anesthesia, block failure, surgical complications, patients who did not complete the 7 days follow up period. Methods: At first a written informed consent was obtained from the patients according to Helsinki declaration. Intrathecal anesthesia applied in sitting position and from the lumbar 4-5 interface with a 25 G, Quincke type needle. Bupivacaine 0.5% (12.5 milligrams) injected intrathecally by an anesthesiologist with the median (first group) or paramedian techniques (second group). The following variables were checked and documented by a researcher unaware of the type of block technique: Primary outcomes were patients' vital signs, the incidence of bradycardia and hypotension, before and at 1, 3, 5 and 10 minutes after spinal block, level of spinal block, nausea and vomiting, amount of ephedrine and atropine usage. Secondary outcomes were post-dural puncture headache (PDPH) on daily checks for 7 days, time to discharge from recovery-out of bed-discharge from hospital.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015060218091N2**

Registration date: **2016-09-24, 1395/07/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-09-24, 1395/07/03

##### Registrant information

###### Name

Fekrat Fereydoon

###### Name of organization / entity

Hormozgan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 76 3334 4009

###### Email address

fereydoon.fekrat@hums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shariati Hospital of Bandar Abbas, Hormozgan University of Medical Sciences

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2016-03-05, 1394/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of two spinal anesthesia approaches: median and paramedian neuraxial blocks on PDPH for cesarean section operations

##### Public title

Comparing two different styles of needle insertion into the spinal space on the complication of headache after

spinal injection of local anesthesia

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: 15-45 years old, elective cesarean section. Exclusion criteria: ASA III-IV, more than one dural puncture, previous PDPH, contraindication for spinal anesthesia, block failure, surgical complications, patients who did not complete the 7 days follow up period.

### **Age**

From **15 years** old to **45 years** old

### **Gender**

Female

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **150**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Hormozgan University of Medical Sciences

##### **Street address**

Joomhoori Islami Blv., Shahid Mohammadi Hospital,

##### **City**

Bandar Abbas

##### **Postal code**

7919915519

#### **Approval date**

2013-07-22, 1392/04/31

#### **Ethics committee reference number**

HEC-92-4-31-1

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Post dural puncture headache after spinal anesthesia

#### **ICD-10 code**

G97.1

#### **ICD-10 code description**

Other reaction to spinal and lumbar puncture

## **Primary outcomes**

### 1

#### **Description**

post- dural puncture headache

#### **Timepoint**

on daily checks for 7 days

#### **Method of measurement**

according to the definition from the International Pain Association, (A headache that occurs in the back of the head or forehead area for a duration of less than 7 days is called post-dural puncture headache)

## **Secondary outcomes**

### 1

#### **Description**

Systolic blood pressure

#### **Timepoint**

Before and 1, 3, 5, 10 minutes after spinal block

#### **Method of measurement**

Non-invasive blood pressure device

### 2

#### **Description**

Diastolic blood pressure

#### **Timepoint**

Before and 1, 3, 5, 10 minutes after spinal block

#### **Method of measurement**

Non-invasive blood pressure device

### 3

#### **Description**

Heart rate

#### **Timepoint**

Before and 1, 3, 5, 10 minutes after spinal block

#### **Method of measurement**

Anesthesia electrocardiographic monitoring equipment

### 4

#### **Description**

level of spinal block

#### **Timepoint**

1, 3, 5, 10 minutes after spinal block

#### **Method of measurement**

level of sensory block with pinprick test

### 5

#### **Description**

Incidence of nausea and vomiting

#### **Timepoint**

During cesarean section and in recovery

**Method of measurement**  
quantitative descriptive

## 6

**Description**  
Amount of ephedrine usage

**Timepoint**  
During cesarean section

**Method of measurement**  
Quantitative descriptive

## 7

**Description**  
Amount of atropine usage

**Timepoint**  
During cesarean section

**Method of measurement**  
quantitative descriptive

## 8

**Description**  
Time to discharge from recovery

**Timepoint**  
Time duration between start of spinal block and discharge from recovery

**Method of measurement**  
Minutes

## 9

**Description**  
Out of bed time

**Timepoint**  
Time duration between start of spinal block and out of bed time

**Method of measurement**  
Minutes

## 10

**Description**  
Discharge from hospital

**Timepoint**  
Time duration between start of spinal block and discharge from hospital

**Method of measurement**  
Minutes

## **Intervention groups**

### 1

**Description**  
Intrathecal anesthesia with the paramedian technique group: will be applied in sitting position and from the lumbar 4-5 interface with a 25 G, Quincke type needle (Dr. J disposable spinal needle K-3 point type luer-lock hub, Dr. Japan CO. Ltd. Tianjin, Hanaco). Bupivacaine 0.5% (12.5 milligram) (Bupivacaine Aguettant sol. Inj. Rachi-anesthesie chloralhydrate hyperbare 20 mg/4 ml,

Mylan S.A.S.) injected intrathecally by an anesthesiologist.

**Category**  
Other

### 2

**Description**  
Intrathecal anesthesia with the median technique group: will be applied in sitting position and from the lumbar 4-5 interface with a 25 G, Quincke type needle (Dr. J disposable spinal needle K-3 point type luer-lock hub, Dr. Japan CO. Ltd. Tianjin, Hanaco). Bupivacaine 0.5% (12.5 milligram) (Bupivacaine Aguettant sol. Inj. Rachi-anesthesie chloralhydrate hyperbare 20 mg/4 ml, Mylan S.A.S.) injected intrathecally by an anesthesiologist.

**Category**  
Other

## **Recruitment centers**

### 1

**Recruitment center**

**Name of recruitment center**

Shariati Hospital of Bandar Abbas

**Full name of responsible person**

Fereydoon Fekrat

**Street address**

Hormozgan, Bandar Abbas, Konsoolgari, Bolvar-e-Shahid Naseri

**City**

Bandar Abbas

## **Sponsors / Funding sources**

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Hormozgan University of Medical Sciences

**Full name of responsible person**

Abdulazim Nejatizadeh

**Street address**

Joomhoori Islami Blv., Deputy of Research Center, Shahid Mohammadi Hospital

**City**

Bandar Abbas

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Hormozgan 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

**Name of organization / entity**  
Hormozgan University of Medical Sciences  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## 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*