# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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**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 electrocardioraphic 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

**Full name of responsible person**

Fereydoon Fekrat

**Position**

Anesthesiology and Intensive care Specialist

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Hashem Jarineshin

**Position**

Assistant Professor of Anesthesiology and Intensive care, Fellowship of Cardiac Surgery Anesthesia

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## Person responsible for updating data

**Contact**

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Anesthesiology, Critical Care and Pain Management Research Center, Hormozgan University of Medical S

**Full name of responsible person**

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**Position**

Specialist in Anesthesiology and Intensive care

**Other areas of specialty/work**

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Joomhoori Islami Blv., Shahid Mohammadi Hospital, Bandar Abbas, Iran

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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*