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
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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

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Name of organization / entity

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Full name of responsible person

Hashem Jarineshin

Position

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

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Fereydoon Fekrat

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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00

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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