Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of median and paramedian approaches to spinal anesthesia in terms of the incidence of headache and backache, and the regression of spinal sensory level in patients undergoing elective cesarean section

Protocol summary

Summary

This study aims to compare median and paramedian approaches to spinal anesthesia in terms of the incidence of headache and backache, and the regression of spinal sensory level. The population includes all patients undergoing elective cesarean section, and the sample includes 138 women aged 18-45 who meet the inclusion criteria to the study. The inclusion criteria includes patients in ASA I and II classes and indication of spinal anesthesia; the exclusion criteria includes patients with a history of preoperative chronic headache and backache, and the puncture of the dura mater more than one time. The study is of a single-blind design. First, the patients will be divided in the operating room into two groups of 69 persons using the table of random numbers. One group will be given median, and the other the paramedian spinal anesthesia (0.7 to 1 mg/kg of %5 lidocaine). Then, the patients will be assessed in terms of headache and backache, and the regression of spinal sensory level by someone unaware of spinal approach, first in the recovery room, and 48 hours later in the ward.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101711147N1**
Registration date: **2013-11-11, 1392/08/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-11-11, 1392/08/20

Registrant information

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Name of organization / entity

University of Medical Sciences Birjand

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2012-09-05, 1391/06/15

Expected recruitment end date

2014-01-30, 1392/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of median and paramedian approaches to spinal anesthesia in terms of the incidence of headache and backache, and the regression of spinal sensory level in patients undergoing elective cesarean section

Public title

Effects of two spinal anesthesia approaches in the incidence of headache, backache, and regression of sensory level after operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- All patients in ASA I and II classes

aged 18-45, 2- indication of spinal anesthesia (lack of peripheral neuropathy, needle insertion site infection, coagulopathy) Exclusion criteria: 1- patients of above ASA I and II classes 2- Chronic back pain and headache 3- General anesthesia concurrent with spinal 4- puncture of the dura mater more than one time

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **138**

Randomization (investigator's opinion)

N/A

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

Ethics Commitee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghaffari Street

City

Birjand

Postal code

9717853577

Approval date

2012-10-06, 1391/07/15

Ethics committee reference number

79677/125

Health conditions studied

1

Description of health condition studied

elective caesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

backache

Timepoint

in the recovery room, every 2 hours after operation; in the ward, every 4 hours after surgery up until 48 hours

Method of measurement

The visual analogue scale (VAS) standard questionnaire will be used to measure backache. In this method, a line with the length of ten centimeters will be used for which one end presupposes numbness and the other end presupposes the worst possible pain. The patient should mark this line to indicate his/her pain severity.

2

Description

headache

Timepoint

in the recovery room, every 2 hours after operation; in the ward, every 4 hours after surgery up until 48 hours

Method of measurement

The visual analogue scale (VAS) standard questionnaire will be used to measure headache. In this method, a line with the length of ten centimeters will be used for which one end presupposes numbness and the other end presupposes the worst possible pain. The patient should mark this line to indicate his/her pain severity.

Secondary outcomes

1

Description

regression of sensory level

Timepoint

10 minutes to 2 hours after surgery in the recovery room

Method of measurement

sensation of coldness and light touch by alcohol

Intervention groups

1

Description

In the first group, a 23- gauge blue needle is inserted at the L4-L5 vertebral level, and lidocaine 5% in a dose of 0.7-1 mg /Kg is injected into the subarachnoid space for spinal anesthesia with median approach (Lidocaine: trade name: Xylocaine, chemical composition: 2-6 dimethyl phenyl, manufactured by Iranian Medicinal Company of Daroo Pakhsh). (In this approach, the spinal needle is inserted from superior boarder of spinous process of inferior vertebra in the midline of the selected space).

Category

Prevention

2

Description
In the second group, a 23-gauge blue needle is inserted at the L4-L5 vertebral level, and lidocaine 5% in a dose of 0.7-1 mg/Kg is injected into the subarachnoid space (Lidocaine: trade name: Xylocaine, chemical composition: 2-6 dimethyl phenyl, manufactured by Iranian Medicinal Company of Daroo Pakhsh). (In this approach, the spinal needle is inserted 1 cm external and 0.5 cm inferior into the selected space with 20 degrees toward the L4-L5 vertebra).

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Mahmoud Ganji
Street address
Anesthesia Group, Operating Room, Valiasr Hospital, Ghaffari Street
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences, Vice Chancellery for Research and Information Technology
Full name of responsible person
Asghar Zarban
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Vice Chancellery for Research, Birjand University of Medical Sciences, Ghaffari St.
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Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences, Vice Chancellery for Research and Information Technology
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

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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