

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

Name

Tahere Khazaei

##### Name of organization / entity

University of Medical Sciences Birjand

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 1431 4657

##### Email address

azar1342@bums.ac.ir

##### 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 Committee 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

##### Street address

Vice Chancellery for Research, Birjand University of Medical Sciences, Ghaffari St.

##### City

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

### Contact

#### Name of organization / entity

Birjand University of Medical Sciences

#### Full name of responsible person

Gholamreza Sharifzadeh

#### Position

Director of Research Affairs

#### Other areas of specialty/work

#### Street address

Vice Chancellery of Research and Information Technology, Birjand University of Medical Sciences, Ghaffari Street

#### City

Birjand

#### Postal code

9717853577

#### Phone

+98 56 1443 1183

#### Fax

+98 56 1444 9011

#### Email

rezamood@yahoo.com

#### Web page address

www.bums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashad University of Medical Sciences

#### Full name of responsible person

Shima Sheibani

#### Position

Anesthesiologist

#### Other areas of specialty/work

#### Street address

No 3, Niloofar St., Sajjad Blvd

#### City

Mashad

#### Postal code

#### Phone

+98 51 1764 7230

#### Fax

#### Email

shimasheibany@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Birjand University of Medical Sciences

#### Full name of responsible person

Gholamreza Sharifzadeh

#### Position

Director of Research Affairs

**Other areas of specialty/work****Street address**

Vice Chancellery of Research and Information  
Technology, Birjand University of Medical Sciences,  
Ghaffari Street

**City**

Birjand

**Postal code**

9717853577

**Phone**

+98 56 1443 1183

**Fax**

+98 56 1444 9011

**Email**

rezamood@yahoo.com

**Web page address**

www.bums.ac.ir

**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*