

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparison of the incidence of post spinal puncture headache between midline and paramedian approaches after cesarean section.

#### Protocol summary

##### Summary

1) Objectives: Postdural puncture headache (PDPH) is a common complication associated with spinal anesthesia. Considering the higher incidence of PDPH in pregnancy and the controversies of the results of previous studies, we decided to compare the incidence of PDPH after spinal anesthesia using Midline & Para-median approaches in cesarean section. 2) Design: After obtaining informed consent patients will be studied in two groups (N=55 in each group). Spinal anesthesia will be performed in all patients in sitting position with 25 gauge Quincke needle in L3-L4 or L4-L5 inter space using 10 mg hyperbaric bupivacaine plus 2.5 micro gram sufentanil. Spinal block will be performed using midline in one study group and paramedian approach in another group of patients. 3) Setting & conduct: Patients will be studied in first, second and third day after operation and the occurrence of headache and backache will be recorded. Severity of pain will be assessed by Visual Analogue Scale of pain (1-10). The patients and the nurse who recorded the vital signs and symptoms like headache and backache are not aware of the grouping. Spinal block will be performed by one anesthesiologist in all patients.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201707028768N6**  
Registration date: **2017-08-18, 1396/05/27**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-18, 1396/05/27

#### Registrant information

##### Name

Mahshid Nikooseresht

##### Name of organization / entity

Hamadan university of Medical Sciences, Faculty of Medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3823 5383

##### Email address

nikooseresht@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for Research and Technology, Hamadan University Of Medical Sciences

#### Expected recruitment start date

2017-09-01, 1396/06/10

#### Expected recruitment end date

2017-12-21, 1396/09/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the incidence of post spinal puncture headache between midline and paramedian approaches after cesarean section.

#### Public title

comparison of post dural puncture headache in midline and paramedian approaches

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: All of the ASA 1 healthy term

parturients (15-45 yr) referring to Fatemeh hospital candidate for Cesarean section were included in the study. Exclusion criteria: chronic hypertension; pre eclampsia; more than one attempt for spinal block; insufficient spinal block that needs more analgesia; allergy to drugs; history of migraine or chronic headache; patients receiving psychiatric drugs

#### **Age**

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

#### **Gender**

Female

#### **Phase**

N/A

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

*No information*

#### **Sample size**

Target sample size: **110**

#### **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**

Committee of Ethics in Research, Hamadan University of Medical Sciences

###### **Street address**

Hamadan University of Medical Science, Shahid Fahmideh street, Hamadan

###### **City**

Hamadan

###### **Postal code**

##### **Approval date**

2017-06-17, 1396/03/27

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

IR.UMSHA.REC.1396.255

### **Health conditions studied**

#### 1

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

post dural puncture headache

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

O74.5

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

Spinal and epidural anaesthesia-induced headache during labour and delivery

### **Primary outcomes**

#### 1

##### **Description**

post spinal headache

##### **Timepoint**

first: second and third day after surgery

##### **Method of measurement**

interview with VAS measurement

### **Secondary outcomes**

#### 1

##### **Description**

Backache

##### **Timepoint**

at first: second and third day after surgery

##### **Method of measurement**

Interview with VAS

#### 2

##### **Description**

Hypotension

##### **Timepoint**

every 2 minutes until delivery and then every 10 minutes

##### **Method of measurement**

BP measurement with automatic blood pressure device

### **Intervention groups**

#### 1

##### **Description**

Intervention 1: In sitting position using Quincke 25 Gauge needle with bevel parallel to sagittal plane from L3-L4 or L4-L5 space with midline approach spinal injection will be performed with 10 mg hyperbaric bupivacaine plus 2.5 microgram sufentanil.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

intervention2: In sitting position using Quincke 25 Gauge needle with bevel parallel to sagittal plane from L3-L4 or L4-L5 space with paramedian approach spinal injection will be performed with 10 mg hyperbaric bupivacaine plus 2.5 microgram sufentanil. In paramedian approach spinal needle was inserted from point 1 cm lateral and 1cm inferior to the superior spinous process of the upper vertebrae with 10-15 angulation toward the midline.

##### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Fatemieh hospital

**Full name of responsible person**

Mahshid Nikooseresht

**Street address**

Pasdaran Street, Shariati square, Hamadan, Iran

**City**

Hamadan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for Research and Technology,  
Hamadan University Of Medical Sciences

**Full name of responsible person**

Saiid Bashirian

**Street address**

Hamadan University of Medical Science, Shahid  
Fahmideh street, Hamadan

**City**

Hamadan

**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 and Technology, Hamadan  
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**

Hamadan University of Medical Sciences

**Full name of responsible person**

Mahshid Nikooseresht M.D

**Position**

Associate Professor of Anesthsiology, Fellowship of  
Pain management

**Other areas of specialty/work**

**Street address**

Anesthesiology Department, Besat hospital, Shahid

Motahari Blvd, Resalat Square, Hamadan

**City**

Hamadan

**Postal code**

6514845471

**Phone**

+98 81 3264 0050

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nikooseresht@umsha.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamadan University of Medical Sciences

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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*