# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of median versus paramedian approach effect on post-dural puncture headache under spinal anesthesia in the elective cesarean section

## Protocol summary

**Study aim**
Comparison of median and paramedian approach effet on post-dural puncture headache under spinal anesthesia in the elective cesarean section

**Design**
In this double-blind clinical trial parallel study (phase 3), 140 pregnant women candidates for cesarean section undergoing spinal anesthesia were included. The patients, by using generated computer numbers, were randomly divided into two groups. In one group the patients underwent intrathecal anesthesia in lumbar intervertebral spaces 4 and 5 with a 25G Quincke needle and 12 mg marcaine 0.5 % by medin method and in another group it was conducted by using the paramedian method.

**Settings and conduct**
The aim of this study was to compare the post-dural puncture headache in women undergoing cesarean section under spinal anesthesia between the median and paramedian methods. The women candidate for cesarean section in Urmia Shahid Motahari Hospital were enrolled in the study. The patient, the researcher, and the outcome assessor were blinded to placing the patients in the median or paramedian groups.

**Participants/Inclusion and exclusion criteria**
In this study, pregnant women candidates for elective cesarean section under spinal anesthesia were enrolled. The patients with a history of migraine, an indication for emergency cesarean section, and a previous history of headache after dural puncture were excluded from the study.

**Intervention groups**
In one group, the patients underwent intrathecal anesthesia in lumbar intervertebral spaces 4 and 5 with a 25G Quincke needle and 12 mg Marcaine 0.5 % by medin method and in another group it was conducted by using the Paramedian method.

**Main outcome variables**
Post-Dural Puncture Headache

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20170516033992N5**
Registration date: **2020-12-26, 1399/10/06**
Registration timing: **retrospective**

Last update: **2020-12-26, 1399/10/06**
Update count: **0**

**Registration date**
2020-12-26, 1399/10/06

**Registrant information**
**Name**
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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+98 44 3222 2010
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2020-02-20, 1398/12/01
**Expected recruitment end date**
2020-06-19, 1399/03/30
**Actual recruitment start date**
2020-02-20, 1398/12/01
**Actual recruitment end date**
2020-06-19, 1399/03/30

**Trial completion date**
2020-06-19, 1399/03/30

**Scientific title**
Comparison of median versus paramedian approach effect on post-dural puncture headache under spinal anesthesia in the elective cesarean section

**Public title**
The effect of median and paramedian approach on post-dural puncture headache

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Pregnant women candidate for elective cesarean section Patients with ASA I and ASA II Cesarean section by spinal anesthesia

**Exclusion criteria:**
Patients with a history of migraine Patients with indication for emergency cesarean section Patients with previous history of headache after dural-puncture

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

**Gender**
Female

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **140**
Actual sample size reached: **140**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients, using random allocation software, were randomly divided into median and paramedian groups. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients were allocated into two groups according to computer-generated numbers.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The patient and the outcome assessor were blinded to the patients' spinal anesthesia approach (anesthetized by median or paramedic approach). An anesthesiologist performed spinal anesthesia in the operating room for randomly selected patients. The patient was only aware that a spinal block was being performed on him, but he was blinded to the needle approach in the median and paramedical method, and the outcome assessor in the later stages was blinded to the type of anesthesia approach (median or paramedian). He only realized that a spinal block had been performed on the patient, but he was blinded to the type of needle approach technique.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Urmia University of Medical Sciences

**Street address**
Urmia University of Medical Sciences; Resalat street; Jahad Blvd; Urmia; Iran.

**City**
Urmia

**Province**
West Azarbaijan

**Postal code**
5714783734

**Approval date**
2020-02-10, 1398/11/21

**Ethics committee reference number**
IR.UMSU.REC.1398.443

## Health conditions studied

### 1

**Description of health condition studied**
Post-Dural Puncture Headache

**ICD-10 code**
G44

**ICD-10 code description**
Other headache syndromes

## Primary outcomes

### 1

**Description**
Post-Dural Puncture Headache

**Timepoint**
In recovery room, ward , time of discharge and up to seven days after surgery

**Method of measurement**
Visual Analogue Scale (VAS)

## Secondary outcomes

### 1

**Description**
Nausea

**Timepoint**
Three times after surgery in recovery, ward and discharge time
**Method of measurement**
Interview with patient

**2**

**Description**
Vomiting
**Timepoint**
Three times after surgery in recovery, ward and discharge time
**Method of measurement**
Interview with patient

**3**

**Description**
Taking Ephedrine (milligram)
**Timepoint**
Recovery
**Method of measurement**
Milligram

**4**

**Description**
Taking atropine
**Timepoint**
Recovery room
**Method of measurement**
Milligram

**5**

**Description**
Anesthetic dermatome
**Timepoint**
Once after surgery
**Method of measurement**
Clinical examination

## Intervention groups

**1**

**Description**
Intervention group: group 1: Spinal anesthesia was conducted in the lumbar intervertebral space 4 and 5 with a 25g Quincke needle and 12 mg Marcaine 0.5 % (Marcain® made by Cobel company) by using the median method.
**Category**
Treatment - Surgery

**2**

**Description**
Intervention group: group 2: Spinal anesthesia was conducted in lumbar intervertebral space 4 and 5 with a 25g Quincke needle and 12 mg Marcaine 0.5 % (Marcain® made by Cobel company) by using the paramedian method.
**Category**
Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Urmia Shahid Motahhari Hospital
**Full name of responsible person**
Dr. Tohid Karami
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## Sponsors / Funding sources

**1**

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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Oroumia University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Oroumia University of Medical Sciences
**Full name of responsible person**
Dr. Tohid Karami
**Position**
Assistant professor
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
Reporting of results as a published article
**When the data will become available and for how long**
After publishing of article
**To whom data/document is available**
Researchers
**Under which criteria data/document could be used**
As published article
**From where data/document is obtainable**
Corresponding author
**What processes are involved for a request to access data/document**
If necessary access to the data can be done through the e-mail address of the corresponding author that will be written in the published article.
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