

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of median and Para median methods in the incidence of Post-Dural-puncture headache in patients undergoing Orthopedic Lower Limb Surgery by spinal anesthesia

#### Protocol summary

##### Study aim

Comparison of median and Para median methods in the incidence of PDPH in patients undergoing Orthopedic Lower Limb Surgery

##### Design

This study will be a double-blind randomized clinical trial with Parallel groups on 60 patients referred to Peymaniyeh Hospital in Jahrom who are undergoing orthopedic lower limb surgery. Patients participating in the study will be divided into two groups by tossing coins.

##### Settings and conduct

Patients referred to Peymaniyeh Hospital in Jahrom who will undergo orthopedic surgery of the lower extremities will be included in the study. Patients participating in the study will be divided into two groups, Madin and Paramedin, by tossing coins. The study participant, researcher, and data collector will be unaware of the type of drug being used.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients referred to Peymaniyeh Hospital in Jahrom who underwent lower limb orthopedic surgery and expressed their consent to participate in the study. Non-entry conditions: includes patients who do not have hemodynamic stability and suffer from acute and chronic pain.

##### Intervention groups

Intervention group 1: Spinal anesthesia in the sitting position of the arachnoid will be performed using a crowford needle with a high gauge 'number' 25 by the median method. Intervention group 2: Spinal anesthesia will be performed using a crowford needle with high gauge 'number' 25 by paramedic method.

##### Main outcome variables

Headache

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210415050976N3**

Registration date: **2021-06-07, 1400/03/17**

Registration timing: **prospective**

Last update: **2021-06-07, 1400/03/17**

Update count: **0**

##### Registration date

2021-06-07, 1400/03/17

##### Registrant information

##### Name

navid kalani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5433 6085

##### Email address

k.navid@juma.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-01, 1400/04/10

##### Expected recruitment end date

2021-11-01, 1400/08/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of median and Para median methods in the incidence of Post-Dural-puncture headache in patients undergoing Orthopedic Lower Limb Surgery by spinal anesthesia

## Public title

Comparison of median and Para median methods in the incidence of Post-Dural-puncture headache in patients undergoing Orthopedic Lower Limb Surgery by spinal anesthesia

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

People who will be operated with spinal anesthesia.  
Hemodynamic stability

### Exclusion criteria:

Chronic pain and cancer Anxiety and mental illness  
Infection at the site of needle entry Coagulation disorders

## Age

From **20 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients participating in the present study will be divided into two groups, Median and Paramedian, by tossing coins.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

For blinding in the present study, the double-blind method is used so that the participant in the study, the researcher and the data collector are not aware of the spinal anesthesia method used.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

## Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

## Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

## City

Jahrom

## Province

Fars

## Postal code

7167758256

## Approval date

2020-02-26, 1398/12/07

## Ethics committee reference number

IR.JUMS.REC.1398.102

## Health conditions studied

### 1

#### Description of health condition studied

Orthopedic patients

#### ICD-10 code

M96.6

#### ICD-10 code description

Fracture of bone following insertion of orthopedic implant, joint prosthesis, or bone plate

## Primary outcomes

### 1

#### Description

Headache

#### Timepoint

Up to 7 days after surgery

#### Method of measurement

Post-Dural-puncture headache criteria

## Secondary outcomes

### 1

#### Description

Vital signs

#### Timepoint

Before spinal anesthesia, after spinal anesthesia and at 5, 15 and 30, 45, 60 and 90 minutes during surgery and in recovery

#### Method of measurement

Monitoring device

## Intervention groups

### 1

#### Description

Intervention group 1: Spinal anesthesia in sitting position and in L3-L4 space after washing the place with betadine and alcohol and topical injection of 1 ml of 2% lidocaine

and then injection of anesthetic (bupivacaine. 5% CC 12.5 mg) in 5 seconds in space The subarachnoid will be performed us

**Category**

Treatment - Other

**2****Description**

Intervention group 2: Spinal anesthesia in sitting position and in L3-L4 space after washing the place with betadine and alcohol and topical injection of 1 ml of 2% lidocaine and then injection of anesthetic (bupivacaine. 5% CC 12.5 mg) in 5 seconds in space The subarachnoid will be performed using a crowford needle with a high gauge 'number' of 25 by the paramedic method.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Peymaniyeh Hospital of Jahrom city

**Full name of responsible person**

Navid Kalani

**Street address**

Jahrom, Shahid Motahari Boulevard, Peymanieh Hospital

**City**

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**Province**

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71677251542

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**Email**

Navidkalani@ymail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Solh joo Kavous

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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**

Jahrom 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**

Jahrom University of Medical Sciences

**Full name of responsible person**

Navid Kalani

**Position**

Research staff

**Latest degree**

Master

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Navid Kalani

**Position**

Research Expert

**Latest degree**

Master

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Jahrom University of Medical Sciences  
**Full name of responsible person**  
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Research Expert  
**Latest degree**  
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**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available