

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

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

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Full name of responsible person

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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**

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Full name of responsible person

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Position

Research Expert

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

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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