Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of Paramedin and Midline methods on headache after dural puncture following spinal anesthesia in patients undergoing orthopedic surgery in Hospital

Protocol summary

Study aim

Determining the effect of two Paramedin and Medline methods on headache after dura rupture in spinal anesthesia in patients undergoing orthopedic surgery in Hospital

Design

A controlled, single-blind, randomized, parallel-group clinical trial was conducted on 160 patients after attrition.

Settings and conduct

This study is an interventional study. Our target population includes orthopedic surgery patients under spinal anesthesia in Imam Khomeini (RA) Jiroft Hospital in 1402. The random assignment is that we consider two groups A and B, after that we put even numbers in group A and odd numbers in group B, and finally one group is named M and the other group is named We consider P. Before the intervention in the two groups (M and P), the initial information of the patients such as age, gender, height and weight, before the start of the anesthesia procedure from the file and items such as the number of dural punctures performed from the patients' anesthesia chart will be entered into the checklist. After that, the intervention and collection of questionnaires in the two groups will be

Participants/Inclusion and exclusion criteria

The inclusion criteria included the age group of 18 to 40 years and people with headaches, people with a ruptured dura mater following spinal anesthesia, and patients undergoing orthopedic surgery. The exclusion criteria included patients with other acute and chronic diseases.

Intervention groups

In the two groups P and M, the intervention is as follows: The midline method (group M) involves passing the needle through the supraspinous, interspinous, and flavum ligaments, while in the paramedian method (group P), puncturing the supraspinous and interspinous ligaments is avoided and only the flavum and dura are punctured.

Main outcome variables

duration of headache; intensity of headache; The nature of the headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200923048817N2**
Registration date: **2025-06-07, 1404/03/17**
Registration timing: **retrospective**

Last update: **2025-06-07, 1404/03/17**
Update count: **0**

Registration date

2025-06-07, 1404/03/17

Registrant information

Name

Ehsan Movahed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3213 3151

Email address

ehsanmovahed89@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-22, 1403/06/01

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of Paramedin and Midline methods on headache after dural puncture following spinal anesthesia in patients undergoing orthopedic surgery in Hospital

Public title
Investigating the effect of Paramedin and Medline methods in headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age group 18 to 40 years People with headaches Suffering from a ruptured dura during spinal anesthesia Patients undergoing orthopedic surgery
Exclusion criteria:
People with other chronic and acute diseases
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
The random sequence is such that for all people undergoing orthopedic surgery, the checklist is completed on different days of the week (both even and odd days) until the desired sample size is reached. Then, each checklist was assigned a code from 1 to 160. The random assignment is such that we consider two groups called A and B, then we randomly place the checklists with even codes in one group and the checklists with odd codes in the other group, and finally, considering that people are randomly placed in two groups, we name one group as M and the other group as P.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants are unaware of their allocation to the two groups
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Jiroft University of Medical Sciences
Street address
Shahid Square
City
Jiroft
Province
Kerman
Postal code
7861615765
Approval date
2023-03-05, 1401/12/14
Ethics committee reference number
IR.JMU.REC.1401.066

Health conditions studied

1

Description of health condition studied
Orthopedic surgery
ICD-10 code
M02.85
ICD-10 code description
Other reactive arthropathies, hip

Primary outcomes

1

Description
The effect of Paramedin and Medline methods on Headache condition
Timepoint
Only after intervention
Method of measurement
Checklist made by the researcher

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The midline method (group M) involves passing the needle through the supraspinous, interspinous, and flavum ligaments

Category
Treatment - Surgery

2

Description
Control group: In the paramedian method (group P), the puncture of the supraspinous and interspinous ligaments is avoided and only the ligament flavum and dura are punctured (punctured).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
in Hospital
Full name of responsible person
Ehsan Movahed
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jeeroft University of Medical Sciences
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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
Jeeroft 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
Jeeroft University of Medical Sciences
Full name of responsible person
Ehsan Movahed
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Ehsan Movahed

Position

Assistant Proffesor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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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

Not applicable

Data Dictionary

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