Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy of Epidural Blood Patch in Treating Dural Puncture-Related Headache after Lower Limb Orthopedic Surgery: A Randomized Clinical Trial

Protocol summary

Study aim

To compare the efficacy and safety of epidural blood patch versus standard conservative management in the treatment of post-Dural puncture headache in patients undergoing lower limb orthopedic surgery

Design

A randomized controlled clinical trial with parallel groups, conducted on 72 patients (36 per group) who are randomly assigned to either the intervention group (epidural blood patch) or the control group (conservative treatment). The outcome assessor and statistical analyst will be blinded to group allocation.

Settings and conduct

Study will be conducted at Al-Najaf Al-Ashraf Hospital in Najaf, Iraq. Patients undergoing lower limb orthopedic surgery under spinal anesthesia who develop PDPH, after confirming eligibility, will be randomly allocated to either the intervention group or the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Randomized patients willing to continue and comply with follow-up. Exclusion criteria: Withdrawal; loss to follow-up; serious adverse events; re-operation/off-protocol invasive treatment; protocol violation; death.

Intervention groups

Intervention Group : Patients undergo an epidural blood patch procedure performed by an anesthesiologist. 20 mL of venous blood is drawn from the patient and slowly injected into the epidural space . After the procedure, the patient remains, with continuous monitoring of vital signs and neurological status. Control Group (Conservative Treatment): receive standard supportive care according to hospital protocols. This treatment includes bed rest, adequate hydration, administration of acetaminophen for pain relief, and caffeine when clinically indicated.

Main outcome variables

Headache severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260428069192N5**
Registration date: **2026-09-28, 1405/07/06**
Registration timing: **prospective**

Last update: **2026-09-28, 1405/07/06**
Update count: **0**

Registration date

2026-09-28, 1405/07/06

Registrant information

Name

Mohamad Sorani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8898 3025

Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-12, 1405/07/20

Expected recruitment end date

2027-01-05, 1405/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of Epidural Blood Patch in Treating Dural Puncture-Related Headache after Lower Limb Orthopedic Surgery: A Randomized Clinical Trial

Public title
Evaluating the Effect of Blood Injection in the Lower Back Area for Treating Headache After Spinal Anesthesia in Lower Limb Orthopedic Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing lower limb orthopedic surgery under spinal anesthesia. Development of post-dural puncture headache (PDPH) according to ICHD-3 criteria. Age between 18 and 65 years. ASA physical status class I or II. Ability to provide written informed consent.

Exclusion criteria:
Coagulation disorders or receiving anticoagulant therapy, Pregnant patients. Local infection at the puncture site or systemic infection. History of chronic headache disorders, migraine, or neurological diseases affecting pain perception. Previous spinal surgery or anatomical abnormalities. Known allergy to study-related medications. Severe cardiovascular, hepatic, renal, or systemic disease. Inability to communicate effectively for reliable pain score assessment.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization in this study will be performed using a pre-generated sequential randomization list. The randomization list will be prepared prior to study initiation by the Principal Investigator using the online randomization platform Randomization.com. This platform utilizes advanced random number generation algorithms to produce unpredictable and unbiased sequences that are fully appropriate for clinical trials. The list will be generated using a random number sequence between ۰ and ۱ with a ۱:۱ allocation ratio. Based on a threshold of ۰.۵, each number will be assigned to one of two groups: D (dexmedetomidine) or P (control). Specifically, if the generated random number is less than ۰.۵, the patient will be allocated to Group D (dexmedetomidine); if the number is ۰.۵ or greater, the patient will be allocated to Group P (control). After the complete list for 72 patients (36 per group) is generated, it will be reviewed and verified by the Principal Investigator to ensure accuracy and the absence of any non-random patterns. The final list will then be stored in a protected file and kept with the Principal Investigator until the start of the study

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, due to the nature of the interventions (invasive epidural blood patch vs. conservative medical treatment), blinding of patients and physicians is not feasible. Patients are aware of the treatment received, and physicians perform the procedure. However, the outcome assessor (VAS measurement) and the statistical analyst will be blinded to group allocation. Data will be received using codes A and B, and unblinding will be performed after analysis completion. In case of accidental disclosure of the patient's group, this will be recorded as a "Breach of Blinding" in the data collection form.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Public Health & Allied Medical Sciences- Tehran University

Street address
No. 17, Bastani Parizi Alley, Ghods St., Enghelab Ave., Enghelab Sq., Tehran

City
Tehran

Province
Tehran

Postal code
1417744361

Approval date
2026-09-08, 1405/06/17

Ethics committee reference number
IR.TUMS.SPH.REC.1405.183

Health conditions studied

1

Description of health condition studied
Post-Dural Puncture Headache

ICD-10 code
G97.1

ICD-10 code description
Other reaction to spinal and lumbar puncture

Primary outcomes

1

Description
"Headache severity" based on VAS at baseline and at 6, 24, 48, and 72 hours post-intervention (0 indicates no pain and 10 indicates the worst imaginable pain).
Timepoint
Baseline and at 6, 24, 48, and 72 hours post-intervention
Method of measurement
Headache severity will be measured using the Visual Analog Scale (VAS). Time to complete symptom resolution will be recorded based on patient report and clinical assessment. Length of stay will be extracted from the patient's medical records.

Secondary outcomes

1

Description
"Need for additional rescue interventions" (repeat epidural blood patch or pharmacological treatment).headache severity more than 6 based on VAS at 6,12,24,72 hours after first intervention.
Timepoint
At 6,12, 24, 72 hours post-intervention.
Method of measurement
Assessing headache severity after the first intervention at 6, 12, 24, and 72 hours after the first intervention.

Intervention groups

1

Description
Intervention group: Epidural Blood Patch will be performed under strict aseptic conditions by an experienced anesthesiologist. Approximately 20 mL of autologous venous blood will be collected from the patient and then slowly injected into the epidural space at or near the previous spinal puncture level. Injection will be stopped immediately if the patient develops significant discomfort, severe back pain, neurological symptoms, or any signs of intolerance during the procedure. Following the intervention, patients will remain under close observation, and vital signs including blood pressure, heart rate, and oxygen saturation will be monitored regularly. Patients will also be evaluated for immediate or delayed procedure-related complications.
Category
Treatment - Other

2

Description
Control group: After fascial closure and before skin closure, 100 mg of tramadol hydrochloride dissolved in 20 mL of normal saline will be infiltrated by the surgeon in a layer-by-layer, multi-site manner at the surgical site. The injection technique is identical to Group A: 5 mL injected into the muscle fascia, 10 mL injected into the subcutaneous tissue (in a fan-shaped manner), and the remaining 5 mL injected into the subdermal layer. Injection will be performed slowly (approximately 2 mL per 10 seconds), and the wound will not be massaged after injection.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Najaf Al-Ashraf teaching hospital
Full name of responsible person
Mohammed Riyadh Hussein
Street address
AL-Jumaiyah st, Al-Najaf, Iraq
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Kordi
Street address
No. 63, Keshavarz Blvd, Tehran.
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Province
Tehran
Postal code
1417653761
Phone
+98 21 6649 1070
Email
tumspr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Sorani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

All data will remain confidential in accordance with the ethical commitment, and only aggregated group-level results will be published in the form of a final article or report

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

Individual participant data will not be shared. The only publishable documents include the aggregated study results in the form of the final manuscript and the Statistical Analysis Plan (SAP). Study results will be disseminated through publication in a reputable national or international peer-reviewed journal in the field of anesthesiology, as well as presentation at relevant scientific conferences

When the data will become available and for how long

Access to SAP: immediately after IRCT registration.
Access to aggregated results (manuscript): submitted

within 12 months of data collection completion; publicly available 6 months post-publication

To whom data/document is available

IPD will not be shared. Aggregated results (manuscript) and SAP will be publicly and unrestrictedly available to all—academic researchers, industry professionals, students, and the public—via the publishing journal and IRCT.

Under which criteria data/document could be used

IPD will not be shared. For use of aggregated results and SAP: 1. Proper citation is mandatory. 2. Direct commercial use is not permitted. 3. Compliance with research ethics is required. 4. No formal request is needed due to open-access publication.

From where data/document is obtainable

Applicants, in order of priority: 1. Publishing journal website (manuscript). 2.. Principal investigator email: mohamad.sorani@gmail.com (additional information). 3. PubMed, Scopus, and Google Scholar.

What processes are involved for a request to access data/document

No application process. Immediate, free download from journal website or Email inquiries

Comments