Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Magnesium Sulfate Versus Gabapentin for Post-Dural Puncture Headache After Spinal Anesthesia for Cesarean Delivery

Protocol summary

Study aim

This study aims to compare Gabapentin and Magnesium Sulfate for reduction of headache intensity in patients who undergo cesarean surgery with spinal anesthesia, in which the dura in punctured and causes Post-Dural Puncture Headache (PDPH).

Design

Single-center, two-arm, parallel-group, Phase 3 randomized superiority clinical trial (n=84; 42 per group) comparing intravenous magnesium sulfate with oral gabapentin for post-dural puncture headache. Randomization will be performed using permuted blocks of four, with blinded outcome assessment and statistical analysis.

Settings and conduct

The trial will be conducted at Ayatollah Mousavi Hospital, Zanjan, Iran. Women who develop post-dural puncture headache following elective cesarean delivery under spinal anesthesia will either receive 600 mg oral gabapentin or 2 g intravenous magnesium sulfate. Headache severity will be assessed using VAS at baseline and 1, 6, 12, 24, and 48 hours after treatment. Rescue analgesic use and adverse events will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18–45 years with American Society of Anesthesiologists (ASA) physical status I–II who developed post-dural puncture headache (PDPH) following spinal anesthesia for elective cesarean delivery and provided written informed consent.
Exclusion criteria: History of preoperative headache, preeclampsia, eclampsia, or hypertension; contraindications to spinal anesthesia; known hypersensitivity to gabapentin or magnesium sulfate; conversion to general anesthesia; development of focal neurological signs; suspected alternative causes of headache; or withdrawal of consent.

Intervention groups

1. Gabapentin 2. Magnesium Sulfate

Main outcome variables

Reduction in Visual Analogue Scale (VAS) for pain experienced by the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261007071343N1**
Registration date: **2026-10-13, 1405/07/21**
Registration timing: **prospective**

Last update: **2026-10-13, 1405/07/21**
Update count: **0**

Registration date

2026-10-13, 1405/07/21

Registrant information

Name

Nazaninsadaat Kakatafti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0001

Email address

nazi.kaka72@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-11, 1405/08/20

Expected recruitment end date

2027-01-10, 1405/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Magnesium Sulfate Versus Gabapentin for Post-Dural Puncture Headache After Spinal Anesthesia for Cesarean Delivery

Public title
Magnesium Sulfate Versus Gabapentin for Headache After Spinal Anesthesia for Cesarean Delivery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
ASA Physical Status I or II Undergoing elective cesarean delivery under spinal anesthesia and subsequently developed a positional headache clinically attributed to Post Dural Puncture Headache Absence of any contraindication for spinal anesthesia No history or report of headache before surgery Absence of Preeclampsia or Eclampsia No known allergy or reaction to Magnesium Sulfate or Gabapentin

Exclusion criteria:
in case spinal anesthesia was failed and converted to general anesthesia developing focal neurological deficits suspecting any alternative cause or explanantion for the headache withdrawal of consent at any stage

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

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **82**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be allocated in a 1:1 ratio to magnesium sulfate or gabapentin using permuted blocks of four. Treatment groups will be coded during outcome assessment and analysis. The unit of randomization will be a patient. Online software from SealedEnvelope.com will be used for creation of the blocks. Allocation concealment will be carried out by sequentially numbered, opaque, sealed envelopes (SNOSE).

Blinding (investigator's opinion)
Double blinded

Blinding description
Because the interventions differ in route of administration (intravenous versus oral), participants and the staff member administering the assigned treatment will not be blinded. A study assistant who's aware of allocation, administers the treatment; whereas the physician assessing outcomes and the statistician were blinded to treatment identity through coded group labels.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
Ayatollah Mousavi Hospital, Gavazang, Zanjan

City
Zanjan

Province
Zanjan

Postal code
4513956183

Approval date
2025-11-25, 1404/09/04

Ethics committee reference number
IR.ZUMS.REC.1404.252

Health conditions studied

1

Description of health condition studied
Postdural puncture headache (PDPH) is a potential complication associated with a lumbar puncture characterized by a bilateral frontal or occipital headache that is worse when the patient is in an upright position, nausea, neck pain, dizziness, visual changes, tinnitus, hearing loss, or radicular symptoms in the arms. These clinical features developed secondary to traction on pain-sensitive structures that experience low cerebrospinal fluid (CSF) pressure, known as intracranial hypotension, following a persistent leak of CSF at the dural puncture site.

ICD-10 code
G97.1

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

Primary outcomes

1

Description
Decrease in headache intensity on a Visual Analogue Scale (VAS)

Timepoint
both at baseline (before treatment, at the time of

diagnosis) and at 1, 6, 12, 24, and 48 hours after receiving the assigned treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (Gabapentin): Participants will receive a single, oral dose of 600 mg gabapentin tablet, manufactured by Tehranchemie pharmaceuticals.

Category

Treatment - Drugs

2

Description

Intervention group: (Magnesium sulfate): Participants will receive a single intravenous dose of 2 g magnesium sulfate ($MgSO_4$), diluted in 100 mL of 0.9% sodium chloride solution. The infusion duration will be 2 hours (1g per hour). Magnesium Sulfate ampule manufactured by Samen Pharmaceuticals will be used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Nazaninsadat Kakatafti

Street address

Ayatollah Mousavi Hospital, Gavazang, Zanjan

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mehrdad Hamidi

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hamidim@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Nazaninsadaat Kakatafti

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Position
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
1. Study Protocol Protocol of the randomized clinical trial comparing intravenous magnesium sulfate and oral gabapentin for post-dural puncture headache following cesarean delivery. Includes study design, eligibility criteria, randomization, interventions, and outcome assessments. 2. Statistical Analysis Plan Statistical analysis plan describing baseline characteristics, longitudinal VAS analysis using generalized estimating equations (GEE), between-group comparisons, rescue analgesic use, and adverse event analysis. 3. Informed Consent Form Blank informed consent form describing the study objectives, procedures, potential risks and benefits, confidentiality, and voluntary participation. No signed forms or identifiable participant information will be shared. 4. Clinical Study Report Final clinical study report containing study methodology, participant characteristics, treatment outcomes, statistical results, adverse events, and study limitations. Sharing arrangements: All four documents will be available in PDF format upon reasonable request to the corresponding author after publication of the main study results.

When the data will become available and for how long
The data will become available after publication of the main study results.

To whom data/document is available
The data approved above to be shared, will be shared upon reasonable request after publication of the main results of the study with researchers active in this field.

Under which criteria data/document could be used
Study documents will be shared upon reasonable written request to the corresponding author after publication of the main results. Requests should specify the applicant’s affiliation, intended purpose, and proposed use. Access will be granted for legitimate academic research, methodological evaluation, evidence synthesis, or educational purposes, subject to review by the corresponding author. Appropriate citation, confidentiality, and non-redistribution are required. No identifiable participant information or signed consent forms will be shared. Individual participant data (IPD) are not included in this sharing plan.

From where data/document is obtainable
Study documents will be available upon reasonable request to the corresponding author after publication of the main results. Requests should preferably be submitted by email. Contact person: Nazaninsadat Kakatafti Email: nazi.kaka72@gmail.com

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

Applicants should email the corresponding author, specifying their name, institutional affiliation, requested documents, and intended use. Requests will be reviewed for scientific relevance and compliance with confidentiality requirements within 10 working days.

Approved documents will be provided electronically in PDF format within 5 additional working days. The expected processing time is 10–15 working days, unless further clarification or institutional approval is required.

Comments