Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

“Effect of Different Doses of Intrathecal Magnesium Sulfate (MgSO4) as an Adjunct for the Prevention of Shivering in Patients Undergoing Spinal Anesthesia”

Protocol summary

Study aim

Determining the effect of different doses of intrathecal magnesium sulfate (MgSO4) as an adjunct to prevent shivering in patients undergoing spinal anesthesia

Design

A single-center, four-arm, parallel-group, blinded, randomized controlled trial involving 172 participants.

Settings and conduct

The trial will be conducted at Bacha Khan Medical Complex, Swabi, Pakistan. Eligible patients undergoing elective surgery under spinal anesthesia will be randomly allocated to one of four groups. Participants and outcome assessors will be blinded to group allocation. The assigned intervention will be administered according to the study protocol. Standard perioperative monitoring and postoperative follow-up will be performed.

Participants/Inclusion and exclusion criteria

1. Inclusion criteria: Age 18-60 years Elective infraumbilical surgeries Hemodynamically stable patient. ASA physical status I–II valid. Written informed consent provided 2. Exclusion criteria: Known allergy/hypersensitivity to MgSO4 Patients on Ca channel blockers or sedative medications Baseline hypothermia or fever Neurological or neuromuscular disorders Severe hepatic, renal, cardiac disease Patients with contraindications to spinal anesthesia, such as infection at the injection site and coagulopathy. Patients requiring conversion to general anesthesia Pregnant patients (exclude if not specifically studying cesarean cases)

Intervention groups

Group A will receive 25 mg intrathecal $MgSO_4$, Group B will receive 50 mg, and Group C will receive 75 mg as an adjunct to spinal anesthesia.

Main outcome variables

Incidence and severity of shivering Adverse effects: Hypotension, Bradycardia, Nausea/vomiting: Sedation level (Ramsay Sedation Scale) Core body temperature Hemodynamic parameters: HR,BP Duration of motor block Duration of sensory block Onset of sensory block: patient satisfaction

General information

Reason for update

Acronym

DIMS (Dose of Intrathecal MgSo4)

IRCT registration information

IRCT registration number: **IRCT20260225068945N1**
Registration date: **2026-08-15, 1405/05/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-15, 1405/05/24**
Update count: **0**

Registration date

2026-08-15, 1405/05/24

Registrant information

Name

Muhammad Farman

Name of organization / entity

Khyber Medical University, Peshawar

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-25, 1405/04/04

Expected recruitment end date

2026-11-05, 1405/08/14

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

Scientific title
"Effect of Different Doses of Intrathecal Magnesium Sulfate (MgSO4) as an Adjunct for the Prevention of Shivering in Patients Undergoing Spinal Anesthesia"

Public title
"Effect of Different Doses of Intrathecal Magnesium Sulfate (MgSO4) as an Adjunct for the Prevention of Shivering in Patients Undergoing Spinal Anesthesia"
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-60 years Elective infraumbilical surgeries ASA physical status I–II valid Hemodynamically stable patient Written informed consent provided
Exclusion criteria:
Known allergy/hypersensitivity to MgSO4 Patients on Ca channel blockers or sedative medications Baseline hypothermia or fever Neurological or neuromuscular disorders Severe hepatic, renal, cardiac disease Patients with contraindications to spinal anesthesia, such as infection at the injection site and coagulopathy Patients requiring conversion to general anesthesia Pregnant patients (exclude if not specifically studying cesarean cases)
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Care provider

Sample size
Target sample size: **172**
Randomization (investigator's opinion)
Randomized
Randomization description
All participants will be given clear information about the study through the clinical trial information sheet. Written consent will be obtained from those who meet the eligibility criteria and agree to participate. Eligible patients will then be randomly assigned to one of three groups using (25 mg, 50 mg, 75 mg) Magnesium Sulfate. Patients in the intervention group will receive spinal anesthesia with 0.5% hyperbaric bupivacaine along with 25mg,50mg,75mg of intrathecal magnesium sulfate diluted in normal saline. Patients in the control group will receive only spinal anesthesia with 0.5% hyperbaric bupivacaine intrathecally. We will record how often shivering occurs during and after surgery and grade its severity using a standard shivering scale. All patients will be closely monitored for blood pressure, heart rate, and any side effects related to intrathecal magnesium sulfate during and after the procedure. • The study drug will be prepared according to group allocation: Group A: 25 mg Mg SO_4 Group B: 50 mg Mg SO_4 Group C: 75 mg Mg SO_4 • Spinal anesthesia will be administered at L3–L4 or L4–L5 using standard technique with 0.5% hyperbaric bupivacaine plus study drug. • Patients will remain unaware of group allocation (single-blind). A trained independent observer, blinded to group allocation, will record all intraoperative observations. • Standard monitoring (ECG, NIBP, SpO_2) will be applied. Parameters will be recorded at predefined intervals (0, 5, 10, 15, 30, 45, 60 minutes): Heart rate Blood pressure Core temperature Shivering score (Wrench scale) • Primary outcome: Incidence and severity of shivering will be assessed using the Wrench shivering scale (0–4). • Secondary Outcomes will be recorded: Onset and duration of sensory block Duration of motor block Sedation level (Ramsay scale) Adverse effects (hypotension, bradycardia, nausea, vomiting) • Management of Adverse Events: Hypotension will be treated with IV fluids and vasopressors Bradycardia will be treated with atropine. The antidote for magnesium sulfate is Calcium gluconate. All adverse events will be recorded in the pro forma • Data will be recorded on a structured questionnaire. Each patient will be assigned a unique ID number. Data will be entered into SPSS software for analysis, and confidentiality will be maintained throughout.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients in the intervention group will receive spinal anesthesia with 0.5% hyperbaric bupivacaine along with 25mg, 50mg, 75mg of intrathecal magnesium sulfate diluted in normal saline. Patients in the control group will receive only spinal anesthesia with 0.5% hyperbaric bupivacaine intrathecally.
Placebo
Used
Assignment
Parallel
Other design features
N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Khyber Medical University
Street address
Phase-V, Hayatabad Peshawar.
City
Peshawar
Postal code
25100

Approval date
2026-06-29, 1405/04/08
Ethics committee reference number
No: KMU/Dean/AHS-26/2305

Health conditions studied

1

Description of health condition studied
Prevention of shivering in patients undergoing spinal anesthesia
ICD-10 code
O89.5
ICD-10 code description
Other complications of spinal and epidural anesthesia during the puerperium

Primary outcomes

1

Description
"Incidence of Postoperative Shivering." The shivering that occurs after spinal anesthesia, it will be measured using the wrench shivering scale intraoperatively and 60 mins postoperatively
Timepoint
Intraoperatively and 60 mins postoperatively
Method of measurement
Temperature and physical examination

Secondary outcomes

1

Description
Onset of sensory block (mins); Time from intrathecal injection to T10 level sensory block
Timepoint
2-6 hours post spinal
Method of measurement
Bilateral sensation to cold/pinprick

2

Description
Duration of Sensory Block (mins); Time from maximum sensory block till regression to S1 level
Timepoint
Every 15 minutes after maximum block till S1 level
Method of measurement
Regression of sensory block using cold/pinprick

3

Description
Duration of motor block (mins); Time from maximum motor block till till recovery of bromage score to "0"
Timepoint
Every 15 minutes after spinal anesthesia till motor recovery
Method of measurement
By using modified Bromage scale till Bromage=0

4

Description
Heart rate changes
Timepoint
Baseline, every 5 min intraoperatively, in recovery
Method of measurement
Measured using continuous ECG monitor

5

Description
Blood pressure changes
Timepoint
Baseline, every 5 min intraoperatively, in recovery
Method of measurement
Noninvasive, using automated monitor

6

Description
Incidence of Hypotension,, Blood Pressure more than 20% decrease from baseline
Timepoint
from intrathecal injection till end of surgery
Method of measurement
Blood Pressure more than 20% decrease from baseline

7

Description
Incidence of bradycardia
Timepoint
From intrathecal injection till end of surgery
Method of measurement
Continuous ECG monitoring, less than 50 beats/min is considered as bradycardia

8

Description
Postoperative pain intensity
Timepoint
At recovery, 2, 4, 6, 12 and 24 hours postoperatively
Method of measurement
VAS/NRS (0-10)

9

Description
Sedation level
Timepoint
At recovery, 30 min, 1, 2, 4 and 6 hours postoperatively
Method of measurement
Ramsay Sedation Scale (RSS)

10

Description
Incidence of adverse effects
Timepoint

Intraoperatively and up to 24 hours postoperatively

Method of measurement

Clinical assessment and documentation of nausea, vomiting, pruritus, respiratory depression and other adverse events

11

Description

Patient satisfaction

Timepoint

At 24 hours postoperatively

Method of measurement

Structured patient satisfaction assessment using a predefined satisfaction scale

Intervention groups

1

Description

Control group: Normal Saline as an adjunct with Bupivacaine SP

Category

Placebo

2

Description

Intervention group 1: 25 mg MgSo4 as an adjunct with Bupivacaine SP

Category

Treatment - Drugs

3

Description

Intervention group 2: 50 mg MgSo4 as an adjunct with Bupivacaine SP

Category

Treatment - Drugs

4

Description

Intervention group 3: 75 mg MgSO4 as an adjunct with Bupivacaine SP

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gulrang International Hospital

Full name of responsible person

Dr Arshad Ali

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N-45, Dheri Alladand, Malakand.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khyber Medical University, Pakistan & Green International University, Pakistan

Full name of responsible person

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Grant name

Research Reimbursement

Grant code / Reference number

Not issued yet, applied for it

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

Yes

Title of funding source

Khyber Medical University, Pakistan & Green International University, Pakistan

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

Khyber Medical University, Peshawar

Full name of responsible person

Muhammad Farman

Position

Lecturer
Latest degree
Master
Other areas of specialty/work
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Effect of different doses of intrathecal MgSO4 as an adjunct for the prevention of shivering in patients undergoing spinal anesthesia
When the data will become available and for how long
After publication for 6 months
To whom data/document is available
Principal Investigator
Under which criteria data/document could be used
N/A
From where data/document is obtainable
via email muhammadfarman782@gmail.com
What processes are involved for a request to access data/document
via email muhammadfarman782@gmail.com
Comments