Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A Comparative Study on the Effect of Intravenous Paracetamol and Intrathecal Meperidine on Shivering in Patients Undergoing Cesarean Section with Spinal Anesthesia

Protocol summary

Study aim
Comparison of the effect of intravenous paracetamol and intrathecal meperidine on shivering in patients undergoing cesarean section under spinal anesthesia

Design
A randomized, triple-blind, placebo-controlled, phase 3 clinical trial with a parallel group design, conducted on 90 patients undergoing cesarean section under spinal anesthesia. Participants will be randomly allocated in equal numbers to receive intravenous paracetamol, intrathecal meperidine, or placebo. Randomization will be centralized and computer-generated using the Sequence Generator tool from random.org.

Settings and conduct
The study will be conducted at Shahid Beheshti Hospital in Isfahan. Patients, healthcare providers, outcome assessors, and the principal investigator will be blinded to the group allocation and intervention type.

Participants/Inclusion and exclusion criteria
Participants will be pregnant women aged 18 to 45 years undergoing elective cesarean section under spinal anesthesia who provide written informed consent. Exclusion criteria include: systemic or local infection at the spinal injection site; underlying conditions such as cardiac, pulmonary, or thyroid disorders; coagulopathies or neurologic diseases; alcohol or drug abuse; psychiatric disorders; body mass index greater than 35; baseline body temperature above 38 or below 36.5 degrees Celsius; use of vasodilators or medications affecting thermoregulation; and known allergy to paracetamol or meperidine.

Intervention groups
Participants will be randomly assigned to three groups. Group 1 will receive 1 gram of intravenous paracetamol. Group 2 will receive 0.1 milligram per kilogram of intrathecal meperidine. The control group will receive 100 milliliters of intravenous normal saline (placebo).

Main outcome variables
Incidence and severity of shivering up to 90 minutes after spinal anesthesia

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240221061070N5**
Registration date: **2025-04-26, 1404/02/06**
Registration timing: **prospective**

Last update: **2025-04-26, 1404/02/06**
Update count: **0**

Registration date
2025-04-26, 1404/02/06

Registrant information

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-04-28, 1404/02/08
Expected recruitment end date
2025-10-30, 1404/08/08
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparative Study on the Effect of Intravenous Paracetamol and Intrathecal Meperidine on Shivering in Patients Undergoing Cesarean Section with Spinal Anesthesia

Public title
Comparison of the Effect of Intravenous Paracetamol and Intrathecal Meperidine on Shivering After Spinal Anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for spinal anesthesia in elective cesarean section ASA class I and II Age between 18 and 45 years
Exclusion criteria:
Patients with systemic infections or infections at the site of spinal block Patients with thyroid disorders Patients with cardiovascular or pulmonary diseases Individuals with coagulation disorders Patients with neurological impairments Individuals with psychiatric disorders Patients with a known history of alcohol dependence or substance abuse Body Mass Index greater than 35 Baseline body temperature above 38°C or below 36.5°C, or those receiving vasodilator medications or drugs that interfere with thermoregulation Known history of hypersensitivity to paracetamol or meperidine
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization will be used to allocate participants into three groups (Group A, Group B, and Group C). This method ensures that each eligible patient has an equal and independent chance of being assigned to any of the groups, thereby minimizing selection bias. The unit of randomization in this study is individual; that is, each patient will be independently and separately assigned to one of the groups. The randomization tool used is the Sequence Generator available on the website www.random.org. In this tool, a random sequence of numbers from 1 to 15 is generated and equally distributed among the three groups A, B, and C. Each number from 1 to 15 is assigned to one of the groups, and the order of these numbers in the list determines the group assignment of the patients. For example, if number 7 appears in the column for Group C, the seventh eligible patient will be assigned to Group C. This process will be repeated for every set of 15 patients. That is, after completing the allocation for the first 15 patients, a new random sequence will be generated for the next 15 patients. This process will continue until the desired sample size is reached. Allocation concealment will be ensured through the use of opaque, sealed, and sequentially numbered envelopes. The generated randomization sequence will be kept confidential within these envelopes. Each envelope will be opened only after confirming the patient's eligibility and obtaining written informed consent. The envelopes will be prepared and maintained by an independent researcher who is not involved in patient recruitment or data collection, in order to prevent any potential allocation bias.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, to minimize bias and enhance the accuracy of outcome measurement, blinding will be implemented comprehensively and at multiple levels. The following individuals will remain blinded to the group allocation of patients throughout the study process: Participants (Patients): All patients enrolled in the study will be unaware of the type of drug administered and their respective treatment group. Additionally, they will not be informed about the allocation of other participants to different groups. It is important to emphasize that all patients will sign a written informed consent form prior to participation and will be fully aware of their involvement in a clinical trial. Therefore, the blinding process will in no way violate ethical principles and will be conducted in full accordance with ethical guidelines. Medical Personnel (Physicians, Anesthesiologists, Surgeons, and Nurses): The study drugs for all groups will be prepared in advance by the principal investigator in identical, unlabeled syringes. These syringes will be delivered to a nursing staff member who has no knowledge of the group allocation or the nature of the drugs. A fully independent anesthesiologist, who is not involved in any part of the study design, implementation, or data analysis and is completely blinded to the type of drug administered and the treatment group of the patients, will be responsible for performing the intrathecal injection. Researchers and Study Team: Researchers responsible for data collection, documentation, and patient follow-up—including anesthesia residents—will be blinded to the type of drug administered and the patients' treatment groups. These individuals will not be involved in the study design, patient allocation, or drug administration, and their role will be limited to recording the outcomes. Outcome Assessors: All assessments of primary and secondary outcomes will be conducted by individuals who are blinded to the treatment groups. These assessors will have no knowledge of the specific interventions received

by the patients and will document outcomes solely based on predefined criteria. Data Analysts: Statistical analysis of the data will be performed by an individual who has access only to the group codes (A, B, C) but is unaware of the actual interventions corresponding to each group. Final unblinding will occur only after the completion of the statistical analysis and confirmation of the results. Manuscript Authors: The authors responsible for drafting the manuscript will also remain blinded to the group allocation until the final stage of data analysis and unblinding. This measure is intended to preserve objectivity in the interpretation of the findings.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences and Health Services, Hazar Jarib St.

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Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2024-02-21, 1402/12/02

Ethics committee reference number
IR.MUI.MED.REC.1402.440

Health conditions studied

1

Description of health condition studied
Shivering after Cesarean section under spinal anesthesia

ICD-10 code
O74.9

ICD-10 code description
Complication of anesthesia during labor and delivery, unspecified

Primary outcomes

1

Description
Incidence of shivering after spinal anesthesia

Timepoint
5, 10, 15, 30, 60, and 90 minutes after spinal anesthesia

Method of measurement
Observation and patient inquiry

2

Description
Severity of shivering after spinal anesthesia

Timepoint
5, 10, 15, 30, 60, and 90 minutes after spinal anesthesia

Method of measurement
Bedside Shivering Assessment Scale (BSAS)

Secondary outcomes

1

Description
Heart rate

Timepoint
5, 10, 15, 30, 60, and 90 minutes after spinal anesthesia

Method of measurement
Vital signs monitoring device

2

Description
Central temperature

Timepoint
5, 10, 15, 30, 60, and 90 minutes after spinal anesthesia

Method of measurement
Core temperature assessment using a standard tympanic thermometer through the external auditory canal

3

Description
Peripheral temperature

Timepoint
5, 10, 15, 30, 60, and 90 minutes after spinal anesthesia

Method of measurement
Axillary temperature measurement using a standard mercury thermometer

4

Description
Level of sedation in patients following spinal anesthesia

Timepoint
Every 15 minutes from the initiation of spinal anesthesia up to 90 minutes post-procedure

Method of measurement
Richmond Agitation-Sedation Scale (RASS)

5

Description
Patient satisfaction with the spinal anesthesia procedure

Timepoint
90 minutes after the initiation of spinal anesthesia

Method of measurement
7-point verbal Likert scale

Intervention groups

1

Description
Intervention group: In the intravenous paracetamol group, each patient will receive 1 gram of paracetamol diluted in 100 mL of normal saline, administered intravenously over 15 minutes. The paracetamol used is in injectable form, commercially available as Apotel manufactured by UNI-PHARMA, or a generic equivalent approved by the Ministry of Health.
Category
Treatment - Drugs

2

Description
Intervention group: In the intrathecal meperidine group, each patient will receive meperidine at a dose of 0.1 mg/kg body weight via intrathecal injection. Following the spinal injection, the patient will also receive 100 mL of intravenous normal saline over 15 minutes, similar to other groups. The meperidine used is in injectable form (Meperidine HCl), commercially available as ALODAN manufactured by G.L.Pharma GmbH, or a generic equivalent approved by the Ministry of Health.
Category
Treatment - Drugs

3

Description
Control group: Each patient in the control group will receive 100 mL of intravenous normal saline over a period of 15 minutes. This solution contains no active pharmaceutical ingredients and serves as a placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Educational and Therapeutic Center
Full name of responsible person
Milad Masaeli
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Shahid Beheshti Hospital, opposite Asman Hotel, Beginning of Shahid Motahari St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholam Reza Asgari
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Research and Technology Vice-Chancellor, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St.
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81746-73461
Phone
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Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Milad Masaeli
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
Not applicable