Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparative Study on the Prophylactic Effects of Different Doses of Intravenous Dexamethasone on Shivering in Patients Undergoing Cesarean Section with Spinal Anesthesia

Protocol summary

Study aim

Comparison of the prophylactic effect of different intravenous doses of dexamethasone on shivering in patients undergoing cesarean section under spinal anesthesia

Design

This is a phase 3 randomized, triple-blind, placebo-controlled clinical trial with a parallel-group design, conducted on 135 patients scheduled for cesarean section under spinal anesthesia. Randomization will be centralized and performed using a random sequence generator available at random.org.

Settings and conduct

The study will be conducted at Shahid Beheshti Hospital in Isfahan. Participants will be equally allocated to three groups receiving either 4 mg of intravenous dexamethasone, 6 mg of intravenous dexamethasone, or placebo. Patients, healthcare providers, outcome assessors, and the principal investigator will be blinded to the group allocation and intervention type.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant women aged 18–45 years, ASA physical status class II, scheduled for elective cesarean section under spinal anesthesia. Exclusion Criteria: Presence of systemic infection or infection at the spinal block site; history of cardiovascular, respiratory, renal, hepatic, or thyroid disease; diabetes mellitus; psychiatric disorders; substance or alcohol abuse; baseline body temperature outside the range of 36.5–38°C; use of vasodilators or medications affecting thermoregulation.

Intervention groups

Participants will be randomly assigned to three groups. The first group will receive 4 mg of intravenous dexamethasone diluted with normal saline to a total volume of 10 mL. The second group will receive 6 mg of intravenous dexamethasone diluted with normal saline to a total volume of 10 mL. The control group will receive 10 mL 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: **IRCT20240221061070N6**
Registration date: **2025-06-12, 1404/03/22**
Registration timing: **prospective**

Last update: **2025-06-12, 1404/03/22**
Update count: **0**

Registration date

2025-06-12, 1404/03/22

Registrant information

Name

Milad Masaeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-11-22, 1404/09/01

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

Scientific title
A Comparative Study on the Prophylactic Effects of Different Doses of Intravenous Dexamethasone on Shivering in Patients Undergoing Cesarean Section with Spinal Anesthesia

Public title
Investigating the Effect of Different Doses of Intravenous Dexamethasone in Preventing Shivering After Spinal Anesthesia in Mothers Undergoing Cesarean Section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for spinal anesthesia in elective cesarean section Patients classified as ASA class 2 Age range between 18 and 45 years
Exclusion criteria:
Patients with systemic infections or infections at the site of spinal block History of cardiopulmonary disease History of hepatic or renal disease Individuals with psychiatric disorders Patients with diabetes mellitus Patients with thyroid disorders Baseline body temperature above 38°C or below 36.5°C Patients with a known history of alcohol dependence or substance abuse Receiving vasodilator medications Receiving drugs that interfere with thermoregulation
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
- Data and Safety Monitoring Board

Sample size
Target sample size: **135**
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 the risk of selection bias. In this trial, the unit of randomization is individual; meaning that each patient will be assigned to one of the groups independently and separately. To generate the random sequence, the Sequence Generator tool available on the website random.org will be used. This tool creates a random sequence of numbers from 1 to 15, which will be 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 how patients are allocated. For example, if number 7 is assigned to Group C, the seventh eligible patient will be placed in Group C. This process will be repeated for every set of 15 patients. That is, after the first 15 patients are allocated, a new random sequence will be generated for the next 15 patients. This procedure will continue until the desired sample size is reached. To ensure allocation concealment, opaque, sealed, and sequentially numbered envelopes will be used. The generated random sequence will be placed confidentially inside these envelopes. Each envelope will only be opened after confirming the patient's eligibility and obtaining written informed consent. The preparation and safekeeping of these envelopes will be carried out by an independent researcher who is not involved in patient recruitment or data collection, in order to prevent any allocation bias.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to minimize bias and enhance the accuracy of outcome measurements, a comprehensive, multi-level blinding strategy will be implemented in this study. The following groups will remain blinded to the treatment allocation of participants throughout the study: Participants (Patients): All patients enrolled in the study will be unaware of the type of drug administered and the treatment group to which they have been assigned. Additionally, they will not be informed about the group allocation of other participants. It is important to note that all patients will sign a written informed consent form prior to enrollment and will be aware of their participation in a clinical trial. Therefore, the blinding process will be conducted in full compliance with ethical principles and does not conflict with any ethical considerations. Healthcare Personnel (Physicians, Anesthesiologists, Surgeons, and Nurses): The study drugs for each group will be prepared in advance by the principal investigator and placed in identical, unlabeled packages. These packages will be delivered to nursing staff who have no knowledge of the drug contents or the method of patient allocation. A separate, independent anesthesiologist—who is not involved in any phase of the study design, implementation, or data analysis and is fully blinded to the type of drug and treatment groups—will be responsible for administering the intrathecal injection. Researchers and Study Team Members: Individuals responsible for data collection, documentation, and patient follow-up—including anesthesia residents—will remain blinded to the type of drug administered and the treatment group. These individuals will not be involved in protocol design, patient allocation, or drug administration, and their sole responsibility will be to record the study outcomes. Outcome Assessors: All assessments of primary and secondary outcomes will be carried out by individuals

who are blinded to the patients' treatment groups. These assessors will have no knowledge of the interventions received by the patients and will record outcomes strictly based on predefined criteria. Data Analysts: Statistical analysis of the data will be performed by an individual who only has access to group codes (A, B, C) and is unaware of the actual interventions corresponding to each group. Final unblinding will occur only after the completion of all statistical analyses and the final confirmation of results. Manuscript Authors: The authors responsible for drafting the manuscript will also remain blinded to group allocation until the final stage of data analysis and unblinding. This measure is taken to preserve objectivity in the interpretation of the study 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.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2024-06-20, 1403/03/31

Ethics committee reference number
IR.MUI.MED.REC.1403.111

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
0, 5, 10, 15, 30, 45, 60, and 90 minutes after spinal anesthesia

Method of measurement
Observation and patient inquiry

2

Description
Severity of shivering after spinal anesthesia

Timepoint
0, 5, 10, 15, 30, 45, 60, and 90 minutes after spinal anesthesia

Method of measurement
Bedside Shivering Assessment Scale (BSAS)

Secondary outcomes

1

Description
Heart rate

Timepoint
0, 5, 10, 15, 30, 45, 60, and 90 minutes after spinal anesthesia

Method of measurement
Vital signs monitoring device

2

Description
Mean arterial pressure

Timepoint
0, 5, 10, 15, 30, 45, 60, and 90 minutes after spinal anesthesia

Method of measurement
Vital signs monitoring device

3

Description
Oxygen saturation

Timepoint
0, 5, 10, 15, 30, 45, 60, and 90 minutes after spinal anesthesia

Method of measurement
Vital signs monitoring device

4

Description
Peripheral temperature

Timepoint
0, 5, 10, 15, 30, 45, 60, and 90 minutes after spinal anesthesia

Method of measurement
Axillary temperature measurement using a standard mercury thermometer

5

Description
Central temperature
Timepoint
0, 5, 10, 15, 30, 45, 60, and 90 minutes after spinal anesthesia
Method of measurement
The core body temperature was measured through the external auditory canal using a tympanic thermometer (Model GENTLE TEMP 520, OMRON Co.).

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Description
Nausea and vomiting
Timepoint
90 minutes after the initiation of spinal anesthesia
Method of measurement
Three-point scale including: Zero = No nausea or vomiting One = Mild to moderate nausea or vomiting not requiring treatment Three = Severe nausea or vomiting requiring treatment

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Description
Patient satisfaction with the spinal anesthesia procedure
Timepoint
90 minutes after the initiation of spinal anesthesia
Method of measurement
Eleven-point numerical scale including: Zero = Complete dissatisfaction Ten = Complete satisfaction

Intervention groups

1

Description
Control group: In this group, each patient will receive 10 milliliters of normal saline intravenously. The injectable solution will be prepared using 0.9% normal saline manufactured by Shahid Ghazi Pharmaceutical Company or an equivalent product approved by the Ministry of Health.
Category
Placebo

2

Description
Intervention group 1: In this group, each patient will receive 4 milligrams of dexamethasone intravenously. The dexamethasone used is an injectable form with the generic name dexamethasone sodium phosphate at a concentration of 4 mg/mL, manufactured by Alborz Darou Pharmaceutical Company or an equivalent product approved by the Ministry of Health. The drug will be diluted and sterilized with normal saline in a 10-mL syringe to a final volume of 10 mL, and will be administered intravenously by an anesthesiologist who is blinded to group allocation.
Category
Treatment - Drugs

3

Description
Intervention group 2: In this group, each patient will receive 6 milligrams of dexamethasone intravenously. The dexamethasone used is an injectable form with the generic name dexamethasone sodium phosphate at a concentration of 4 mg/mL, manufactured by Alborz Darou Pharmaceutical Company or an equivalent product approved by the Ministry of Health. The drug will be diluted and sterilized with normal saline in a 10-mL syringe to a final volume of 10 mL, and will be administered intravenously by an anesthesiologist who is blinded to group allocation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Educational and Therapeutic Center
Full name of responsible person
Milad Masaeli
Street address
Shahid Beheshti Hospital, opposite Asman Hotel, Beginning of Shahid Motahari St.
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Isfahan
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Isfehan
Postal code
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Email
drmilmas@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholam Reza Asgari
Street address
Research and Technology Vice-Chancellor, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St.
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Isfehan
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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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Shahid Beheshti Hospital, opposite Asman Hotel, Beginning of Shahid Motahari St.

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Person responsible for scientific 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

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Person responsible for updating data

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Esfahan University of Medical Sciences

Full name of responsible person

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Position

Associate professor

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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