Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effect of intravenous lidocaine on reducing shivering after spinal anesthesia in cesarean section patients referred to Imam Khomeini Hospital in Sari A double-blind clinical trial

Protocol summary

Study aim
To investigate the effect of intravenous lidocaine on the severity of post-spinal anesthesia shivering in patients undergoing cesarean section.

Design
A randomized, double-blind, placebo-controlled clinical trial with two parallel groups.

Settings and conduct
The study will be conducted at Imam Khomeini Hospital, Sari, Iran. Patients will undergo cesarean section under spinal anesthesia, and the assigned study solution will be administered following successful delivery of the neonate. Shivering severity, hemodynamic parameters, sedation level, body temperature, and nausea and vomiting will be assessed at 15, 30, 60, and 90 minutes.

Participants/Inclusion and exclusion criteria
patients undergoing cesarean section under spinal anesthesia, aged 18–65 years and classified as ASA physical status I–II, will be enrolled after providing written informed consent and meeting the eligibility criteria. Patients meeting any exclusion criteria will not be included.

Intervention groups
Intervention group: Intravenous lidocaine at 1 mg/kg body weight. Control group: An equivalent volume of placebo (normal saline).

Main outcome variables
The primary outcome is the severity of post-spinal anesthesia shivering, assessed using a four-point scale at 15, 30, 60, and 90 minutes. Secondary outcomes include hemodynamic changes, body temperature, sedation level, and the incidence of nausea and vomiting.

General information

Reason for update
Acronym

IRCT registration information
IRCT registration number: **IRCT20250630066304N8**
Registration date: **2026-10-12, 1405/07/20**
Registration timing: **prospective**

Last update: **2026-10-12, 1405/07/20**
Update count: **0**

Registration date
2026-10-12, 1405/07/20

Registrant information
Name
Samira Sobhani
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-10-23, 1405/08/01
Expected recruitment end date
2027-03-20, 1405/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effect of intravenous lidocaine on reducing shivering after spinal anesthesia in cesarean section

patients referred to Imam Khomeini Hospital in Sari A double-blind clinical trial

Public title
Intravenous lidocaine for shivering after spinal anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 65 years ASA physical status classification I or II Requirement for spinal anesthesia for Cesarean section Informed written consent for participation in the study
Exclusion criteria:
History of hypersensitivity to lidocaine or other local anesthetics Presence of severe cardiovascular disease Neurological or psychiatric disorders affecting study results History of seizures
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
A computer-generated randomization sequence is going to be prepared using IBM SPSS Statistics to allocate participants to the two study groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study solutions will be prepared in identical volumes and coded to conceal treatment allocation. Participants and outcome assessors will remain unaware of group assignments. The severity of post-spinal shivering and other study outcomes will be assessed at the prespecified time points. Group codes will remain concealed until data collection and statistical analysis are completed. If emergency unblinding is required for patient safety, it will be performed according to the study protocol.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Mazandaran University of Sari Medical Sciences, Imam Hospital
Street address
Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
48166-33131
Approval date
2026-06-20, 1405/03/30
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1405.052

Health conditions studied

1

Description of health condition studied
Shivering after Spinal Anesthesia
ICD-10 code
O29.5X
ICD-10 code description
Other complications of spinal and epidural anesthesia during pregnancy

Primary outcomes

1

Description
severity of post-spinal anesthesia shivering
Timepoint
15,30,60 and 90 minutes after the spinal anesthesia
Method of measurement
a four-point scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intravenous lidocaine at 1 mg/kg body weight.
Category
Treatment - Drugs

2

Description

Control group: An equivalent volume of placebo (normal saline).

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Sari

Full name of responsible person
Samira Sobhani

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Imam Khomeini Medical Training Center, Amir Mazandarani Boulevard, Sari, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Ahmadali Enayati

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Grant name

Grant code / Reference number

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

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Samira Sobhani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available

Title and more details about the data/document
Individual participant data, including demographic and clinical characteristics, post-spinal anesthesia shivering severity, hemodynamic parameters, body temperature, sedation level, and the incidence of nausea and vomiting in patients undergoing cesarean section. Data will be stored confidentially using coded identifiers.

When the data will become available and for how long
Data will be made available upon reasonable request after completion of the study and publication of the main results, subject to ethical and confidentiality requirements. The availability period will follow the university’s research data retention policies.

To whom data/document is available
Qualified researchers and members of the scientific community with a valid research request may request access to the data, subject to participant confidentiality requirements.

Under which criteria data/document could be used
Data may be used only for valid scientific and research purposes in accordance with research ethics principles. Use is subject to approval of the request, protection of participant confidentiality, and a prohibition on attempts to re-identify participants.

From where data/document is obtainable
The data may be requested from the principal investigator or research team at Imam Khomeini Hospital, Sari, Iran.

What processes are involved for a request to access data/document
A written request should describe the research objectives, proposed use of the data, and measures to protect confidentiality. The request will be reviewed by the principal investigator and, where necessary, the relevant research or ethics authorities. Access will be granted only after approval and agreement to comply with confidentiality requirements.

Comments