Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy And Safety of Prophylactic Rectal Diclofenac in Preventing Post-Anesthesia Shivering During Cesarean Section: A Randomized Double-Blind Placebo-Controlled Clinical Trial

Protocol summary

Study aim

Determination of the effect of rectal diclofenac suppository prophylaxis on shivering after cesarean section

Design

Study Design: Double-blind randomized controlled trial Two parallel groups (intervention vs placebo) Single-center study Sample Size: 100 total participants (50 per group) Calculated based on: Type I error (α) = 0.05 Power = 80% Expected minimum difference of 25% in post-anesthesia shivering between groups Randomization: Simple randomization method Individual-level randomization (not cluster) Computer-generated random numbers Double-blinding implemented (both patients and post-operative observers are blinded to group allocation) Study Groups: Intervention Group: Receives 100mg rectal diclofenac suppository 10 minutes before surgery Standard anesthesia protocol Control Group: Receives placebo suppository 10 minutes before surgery Same standard anesthesia protocol

Settings and conduct

This double-blind randomized controlled trial will be conducted at a single center. The study will involve women aged 18-40 years undergoing cesarean section with ASA status I or II. The operating room temperature will be maintained at 22-24°C throughout the procedures.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women aged 18-40 years Undergoing cesarean section ASA status I or II Willing to participate in the study Exclusion Criteria: Allergy to diclofenac Cardiovascular disease Hypertension Diabetes Kidney disease Chronic lung disease Liver disease History of alcohol consumption Body temperature below 36°C Body temperature above 38°C

Intervention groups

Receives 100mg rectal diclofenac suppository 10 minutes before surgery

Main outcome variables

Determination of the effect of rectal diclofenac suppository prophylaxis on shivering after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241115063724N1**
Registration date: **2024-12-31, 1403/10/11**
Registration timing: **prospective**

Last update: **2024-12-31, 1403/10/11**
Update count: **0**

Registration date

2024-12-31, 1403/10/11

Registrant information

Name
Golnaz Mesbah
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2271 4869
Email address
golnazmesbah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-08-21, 1404/05/30

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

Scientific title
Efficacy And Safety of Prophylactic Rectal Diclofenac in Preventing Post-Anesthesia Shivering During Cesarean Section: A Randomized Double-Blind Placebo-Controlled Clinical Trial

Public title
Efficacy Prophylactic Rectal Diclofenac in Preventing Post-Anesthesia Shivering During Cesarean Section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18-40 years Undergoing cesarean section ASA status I or II Willing to participate in the study
Exclusion criteria:
Allergy to diclofenac Cardiovascular disease Hypertension Diabetes Kidney disease Chronic lung disease Liver disease History of alcohol consumption Body temperature below 36°C Body temperature above 38°C
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
This research is structured as a double-blind randomized controlled trial utilizing simple randomization with computer-generated random numbers. The randomization occurs at the individual patient level, where eligible participants (women aged 18-40 years undergoing cesarean section with ASA status I or II) are randomly allocated into one of two study arms. The intervention group receives a 100mg rectal diclofenac suppository 10 minutes prior to surgery, while the control group receives a placebo suppository. To maintain the integrity of the double-blind design, both the patients and the post-operative ward observers are kept unaware of group assignments.
Blinding (investigator's opinion)
Double blinded
Blinding description
This clinical trial employs a double-blind design with multiple levels of blinding to ensure the validity of results. The blinding process encompasses both the study participants and the healthcare providers involved in post-operative care. The study maintains blinding through the use of identical-appearing suppositories for both the active drug (100mg diclofenac) and placebo groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Tehran Province, Tehran, District 1, Daneshjou Blvd, Q9XV+XG7, 19839 69411
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2024-11-05, 1403/08/15
Ethics committee reference number
IR.SBMU.MSP.REC.1403.445

Health conditions studied

1

Description of health condition studied
Post-cesarean section shivering is the involuntary shaking or shivering that happen due to several reasons, including the effects of anesthesia, a drop in body temperature during surgery, and the body's response to stress and changes in the blood flow following cesarean section
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Comparison of Tsai and Chu scores between the intervention and placebo groups after cesarean section
Timepoint
Patients are observed at least for 30 minutes immediately after surgery while covered with a blanket and the shivering score will be recorded every 15

minutes until recovery from anesthesia

Method of measurement

Shivering assessment is done using the Tsai and Chu scale (0-4)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receives 100mg rectal diclofenac suppository 10 minutes before surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohadaye Tajrish Hospital

Full name of responsible person
Leila Nazari

Street address
Tehran Province, Tehran, Shahrdari St, Shohadaye Tajrish Hospital

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Tehran

Province
Tehran

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Web page address
https://shmc.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed Hasan Sadoogh

Street address
Tehran, Velenjak, Daneshjoo Boulevard, Erabi Street, Shahid Beheshti University of Medical Sciences

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Golnaz Mesbah

Position
Medical Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position
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Latest degree
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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
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
The study will share de-identified individual participant data (IPD) including demographic information, clinical measurements, and treatment outcomes through a secure clinical trial data repository within 12 months after study completion. Access will be granted to qualified researchers who submit methodologically sound proposals and sign a data use agreement. Essential study documentation including the protocol, statistical analysis plan, informed consent form, and clinical study report will be made available through an institutional repository with DOI assignment within 6 months of study completion. The primary manuscript and supplementary materials will be published in a peer-reviewed journal, with results also posted to the clinical trial registry within 12 months of completion. Raw data including de-identified datasets, data dictionary, and codebook will be shared through a secure repository upon reasonable request after publication.
When the data will become available and for how long
The primary manuscript and supplementary materials will be published in a peer-reviewed journal, with results also posted to the clinical trial registry within 12 months of completion.
To whom data/document is available
Access will be granted to qualified researchers who submit methodologically sound proposals and sign a data use agreement.
Under which criteria data/document could be used
Access to study data and documents will be granted to qualified researchers affiliated with academic or research institutions who submit a methodologically sound research proposal. All requests will undergo review by a designated committee including principal investigators and institutional representatives within 4-6 weeks. The evaluation will consider the scientific validity, researcher qualifications, potential public health benefit, and feasibility of the proposed analysis. Approved users must sign a data use agreement specifying that data can only be used for the approved research purpose, no re-identification of participants will be attempted, proper citation of the original study is required, and results from secondary analyses must be shared with the original research team. The data must be stored securely with access limited to approved team members, and proper data destruction is required after project completion. Data will be available within 12 months of study completion, with access duration limited to the approved project timeline.
From where data/document is obtainable
The data and documents will be available through direct contact with the principal investigator, Dr. Leila Nazari, who will serve as the primary point of contact for data sharing requests. Here are the specific contact details and procedures: Contact Information: • Primary Contact: Dr. Leila Nazari (Principal Investigator) • Department: Obstetrics and Gynecology • Institution: Shahid Beheshti University of Medical Sciences • Email: nazari@sbmu.ac.ir Access Procedures: 1. Interested researchers should submit their data access requests via email to the principal investigator 2. The request should include: o A brief research proposal o Intended use of the

data o Researcher credentials o Institutional affiliation o Timeline for data use The principal investigator will review requests within 4-6 weeks and provide access to approved researchers through secure file sharing platforms or institutional repositories.

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

The request should include: o A brief research proposal o Intended use of the data o Researcher credentials o Institutional affiliation o Timeline for data use The principal investigator will review requests within 4-6 weeks and provide access to approved researchers through secure file sharing platforms or institutional repositories.

Comments