# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparative study of the preventive effect of intravenous meperidine and intravenous dexmedetomidine on analgesia after cesarean section

## Protocol summary

**Study aim**
Evaluation and comparison of the preventive effect of intravenous dexmedetomidine and meperidine on the intensity and incidence of postoperative pain following cesarean section under spinal anesthesia

**Design**
A phase III randomized, triple-blind, parallel-group clinical trial including 120 patients. Randomization was performed in blocks of 15 using the random.org website.

**Settings and conduct**
This randomized, triple-blind clinical trial is conducted at Shahid Beheshti Hospital of Isfahan. After obtaining written informed consent, eligible patients undergo spinal anesthesia. The participants are then randomly assigned to one of three groups to receive the designated intravenous drug. The study drugs are prepared by the anesthesiologist in identical and coded syringes. Following delivery, pain intensity, side effects, and patient satisfaction are assessed for up to eight hours.

**Participants/Inclusion and exclusion criteria**
Women aged 18 to 45 years with ASA class II status who are admitted to Shahid Beheshti Hospital of Isfahan for elective cesarean section under spinal anesthesia will be included in the study. Exclusion criteria consist of cardiovascular, pulmonary, renal, hepatic, or psychiatric diseases; diabetes or thyroid disorders; body temperature outside the range of 36.5–37.5 °C; history of alcohol or substance abuse; use of vasodilator medications; or the need for intraoperative blood transfusion. Patients experiencing spinal anesthesia failure or any unexpected complications during the procedure will be excluded from the study.

**Intervention groups**
1.Dexmedetomidine group: 10 µg of IV dexmedetomidine 2.Meperidine group: 10 mg of IV meperidine 3.Control group: 10 mL of IV normal saline

**Main outcome variables**
Pain intensity; need for additional analgesics; adverse events (hypotension, bradycardia, nausea/vomiting); patient satisfaction level.

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20240221061070N8**
Registration date: **2025-11-18, 1404/08/27**
Registration timing: **prospective**

Last update: **2025-11-18, 1404/08/27**
Update count: **0**

**Registration date**
2025-11-18, 1404/08/27

**Registrant information**
**Name**
Milad Masaeli
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2025-11-22, 1404/09/01
**Expected recruitment end date**
2026-02-20, 1404/12/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparative study of the preventive effect of intravenous meperidine and intravenous dexmedetomidine on analgesia after cesarean section

**Public title**
Effect of Meperidine and Dexmedetomidine on Post-Cesarean Analgesia

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Pregnant women classified as ASA II Age range between 18 and 45 years Candidates for elective cesarean section under spinal anesthesia Written informed consent to participate in the study No known allergy to the study medications (meperidine or dexmedetomidine)

**Exclusion criteria:**
Known cardiac, pulmonary, hepatic, or renal disease Psychiatric disorders, diabetes mellitus, or thyroid dysfunction Body temperature at operating room admission < 36.5 °C or > 37.5 °C History of alcohol or substance abuse Use of vasodilator medications Requirement of intraoperative blood transfusion

**Age**
From **18 years** old to **45 years** old

**Gender**
Female

**Phase**
Bioequivalence

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**
Target sample size: **120**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Participants are randomly assigned to one of three groups (meperidine, dexmedetomidine, or placebo) using block randomization (blocks of 15) generated through random.org. Allocation concealment is maintained through sealed opaque envelopes prepared by an independent statistician. The study is triple-blind (investigator, participants, and outcome assessor).

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
This clinical trial is conducted under a triple-blind design to ensure unbiased assessment of outcomes. The study drugs (meperidine, dexmedetomidine, and normal saline) are prepared by an anesthesiologist not involved in data collection, using identical, coded syringes labeled A, B, and C. Only the anesthesiologist and the randomization coordinator know the allocation code until data analysis is completed. The principal investigator, participants, clinical caregivers, outcome assessor (VAS), and data analyst are all blinded to group assignment. At the end of the study, the randomization codes are disclosed by an independent statistician for final data analysis.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

**Street address**
Al-Zahra Hospital, Daneshgah Street.

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673461

**Approval date**
2025-10-05, 1404/07/13

**Ethics committee reference number**
IR.ARI.MUI.REC.1404.175

## Health conditions studied

### 1

**Description of health condition studied**
Post-Cesarean Pain (Postoperative Pain after Cesarean Section)

**ICD-10 code**
G89.18

**ICD-10 code description**
Other acute postprocedural pain

## Primary outcomes

### 1

**Description**
Postoperative pain intensity after cesarean section

**Timepoint**
At baseline (0 hour), 2 hours, 4 hours, 6 hours, and 8 hours after surgery

**Method of measurement**
The primary variable (postoperative pain intensity) will

be measured using the Visual Analogue Scale for pain assessment. This scale consists of a 10-centimeter horizontal line with “no pain” marked at one end (score 0) and “the worst pain imaginable” at the other end (score 10). At each predefined postoperative time point (0, 2, 4, 6, and 8 hours after the cesarean section), the patient will indicate the intensity of pain by marking a point on the line corresponding to their perceived pain level. The score is obtained by measuring the distance in centimeters from the “no pain” anchor to the patient’s mark. Before surgery, all participants will be instructed on how to use the scale to ensure a consistent and valid understanding of pain rating across subjects.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Control group: 10 mL of intravenous normal saline
**Category**
Placebo

### 2

**Description**
Intervention group: 10 mg of intravenous meperidine (Meperidine HCl 10 mg/10 mL)
**Category**
Prevention

### 3

**Description**
Intervention group: 10 µg of intravenous dexmedetomidine (Dexmedetomidine HCl 10 µg/10 mL)
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Beheshti educational and therapeutic center
**Full name of responsible person**
Milad Masaeli
**Street address**
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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
**Street address**
Research and Technology Vice-Chancellor, No. 4 Building, Isfahan University of Medical Sciences and Health care Service, Hazar Jerib St.
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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**
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
**Street address**
Apposite of Asman Hotel, The beginning of Shahid Motahari St., Felezzi Bridge, Isfahan
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
The data is private

**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**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
All information except for the names and personal information of the participants

**When the data will become available and for how long**
6 months after the publication of the results

**To whom data/document is available**
Academic researchers by the reason

**Under which criteria data/document could be used**
If it is for scientific purposes

**From where data/document is obtainable**
They should send an Email to drmilmas@gmail.com, and after providing their reasons, the required information will be sent to them

**What processes are involved for a request to access data/document**
They should send an Email to drmilmas@gmail.com, and after providing their reasons, the required information will be sent to them

**Comments**