

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Oct 2026

Comparison of intravenous Dexmedetomidine and Meperidine in the treatment of post spinal shivering in cesarean section

Protocol summary

Study aim

Determination of the effect of intravenous Dexmedetomidine and Meperidine in the treatment of post spinal shivering in cesarean section.

Design

This randomized, double-blind clinical trial with parallel groups and phase 2-3 will be conducted on 246 pregnant patients aged 18 to 46 who are candidates for caesarean section under spinal anesthesia who experience shivering after anesthesia, and block randomization is used for randomization.

Settings and conduct

After spinal anesthesia and ensuring sensory block at the T4 level, all patients will be prepped and covered with a double layer of surgical drapes and the surgery will begin. During surgery and recovery, patients will be checked for shivering. In case of shivering in group A, patients will receive meperidine 0.5mg/kg and in group B, patients will receive dexmedetomidine 0.5ug/kg after umbilical cord clamping with a total volume of 20ml within 10 minutes. Then the intensity of shivering, blood pressure, heart rate, spo2, and sedation score will be measured at intervals of 5, 10, 15, 20, and 30 minutes after the administration of the drugs. Nausea, vomiting, and dizziness will also be checked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Withdrawal from participation of the study; 18 to 46 years old; Parturient patients with post spinal shivering. Exclusion criteria: Withdrawal from participation of the study; Cardiac and pulmonary diseases; Eclampsia and preeclampsia; Contraindications of spinal anesthesia; History of seizures or Parkinson; Intraoperative transfusion; Taking sedative and vasodilator drugs; Dysautonomia; Allergy to the drugs.

Intervention groups

After spinal anesthesia and the start of surgery, if there is shivering, the patients are randomly assigned to one of the two groups of meperidine and dexmedetomidine.

Main outcome variables

Intensity of [post spinal shivering].

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N27**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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manouchehrian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of intravenous Dexmedetomidine and Meperidine in the treatment of post spinal shivering in cesarean section

Public title
postoperative shivering

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Conscious consent to participate in the study Parturients candidate for cesarean section under spinal anesthesia 18 to 46 years old Patients with shivering during surgery or in recovery with a grade of more than 2
Exclusion criteria:
Withdrawal from participation of the study Cardiac and pulmonary, hepatic, renal diseases, hypertension, diabetes, arrhythmia and heart failure Eclampsia and preeclampsia Contraindications of spinal anesthesia (high ICP, hypovolemia, anemia, coagulation disorders) History of seizures or Parkinson's disease Intraoperative transfusion History of taking sedative-hypnotic and vasodilator drugs Dysautonomia Allergy to the drugs

Age
From **18 years** old to **46 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **246**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the quadruple Block Randomization method. For this purpose, we prepare four sheets of paper. Write the letter A on two sheets and the letter B on the other two sheets. Mix the sheets together and place them in the desk drawer. With the referral of each eligible patient, one of the sheets is randomly taken out and based on this sheet is A or B, it will be assigned to one of the two groups of Dexmedetomidine and Meperidine. After randomly pulling out all four sheets, all the papers are returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
After spinal anesthesia and the start of surgery and

delivery of the baby, if the patient experiences shivering, she will receive one of the drugs Dexmedomidine and Meperidine, which is prepared in syringes with the same size and shape and labeled A and B by the nurse of anesthesia who is not involved in collecting or recording data.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Mahdieh Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2022-07-23, 1401/05/01

Ethics committee reference number

IR.UMSHA.REC.1401.389

Health conditions studied

1

Description of health condition studied

Treatment of intra or postoperative shivering

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description

Shivering intensity

Timepoint

In 5,10,15 and 20 minutes after the administration of meperidine and dexmedomidine drugs.

Method of measurement

Observation based on crossley score of shivering

Secondary outcomes

1

Description

Systolic and diastolic blood pressure

Timepoint

Before injection and in 5,10,15,20 and 30 minutes after the administration of shivering drugs

Method of measurement

Non-invasive automatic barometric device

2

Description

Heart Rate

Timepoint

Before injection and in 5,10,15,20 and 30 minutes after the administration of shivering drugs.

Method of measurement

Pulse oximetry

3

Description

Percentage of arterial oxygen saturation

Timepoint

Before injection and in 5,10,15,20 and 30 minutes after the administration of shivering drugs.

Method of measurement

Pulse oximetry

4

Description

Nausea & vomiting

Timepoint

After the injection of drugs for the treatment of shivering until the patient leaves the operating room

Method of measurement

Observation

5

Description

sedation score

Timepoint

Before injection and in 5,10,15,20 and 30 minutes after the administration of shivering drugs.

Method of measurement

Ramsy sedation score

6

Description

Dizziness

Timepoint

After the injection of drugs for the treatment of shivering until the patient leaves the operating room.

Method of measurement

Question from the patient

Intervention groups

1

Description

Intervention group: After spinal anesthesia and ensuring sensory block at the T4 level, all patients will be prepped and covered with a double layer of surgical drapes and the surgery will begin. During surgery and recovery, patients will be checked for shivering. In case of shivering in group A, patients will receive meperidine 0.5mg/kg after umbilical cord clamping with a total volume of 20ml within 10 minutes.

Category

Treatment - Drugs

2

Description

Intervention group: After spinal anesthesia and ensuring sensory block at the T4 level, all patients will be prepped and covered with a double layer of surgical drapes and the surgery will begin. During surgery and recovery, patients will be checked for shivering. In case of shivering in group B, patients will receive dexmedetomidine 0.5ug/kg after umbilical cord clamping with a total volume of 20ml within 10 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nahid Manouchehrian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Hamedan 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
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Full name of responsible person
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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

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available