Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of intravenous injection of pethidine and dexmedetomidine to prevent shivering after cesarean section under spinal anesthesia

Protocol summary

Study aim
Determining the effect of intravenous injection of pethidine and dexmedetomidine to prevent shivering after cesarean section under spinal anesthesia

Design
A randomized double-blinding clinical trial, with the parallel groups

Settings and conduct
This randomized double-blind clinical trial is performed in Al-Zahra and Shahid Beheshti hospitals in Isfahan. In this study, 90 pregnant women will be candidates for elective cesarean section and will be randomly divided into 3 parallel groups. The three groups were then given normal saline, dexmedetomidine and pethidine, respectively, immediately after anesthesia.

Participants/Inclusion and exclusion criteria
Inclusion criteria include pregnancy, elective cesarean section with ASA score 1 and 2, not addicted to drugs and alcohol based on the patient's statement. Exclusion criteria include previous use of painkillers, drugs and alcohol, history of severe cardiovascular disease, History of kidney and liver diseases, presence of drug allergy, seizures, and Having fever.

Intervention groups
A 15 ml/kg of lactated ringer is injected for All patients, which has reached a temperature of 37 ° C. Oxygen is applied with a flow rate of 5 liters/minute, and patients are covered with a thin coating that does not actively warm them. The room temperature is kept at 24 ° C and there is no heating device there. Spinal anesthesia is performed in the lateral decubitus position of the and at the L3 and L4 levels in the midline after the umbilical cord clamp. The patients are placed in the supine position with some rotation to the right. Then, patients in the control group, first and second intervention groups, were given the normal saline, 1 µg / kg dexmedetomidine, and 0.25 mg of pethidine respectively.

Main outcome variables
Tympanic temperature (as central temperature); Axillary temperature (as the peripheral body temperature); Intensity of shivering

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N5**
Registration date: **2020-10-05, 1399/07/14**
Registration timing: **prospective**

Last update: **2020-10-05, 1399/07/14**
Update count: **0**

Registration date
2020-10-05, 1399/07/14

Registrant information

Name
Asieh Maghami Mehr

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
2020-10-22, 1399/08/01

Expected recruitment end date
2020-12-21, 1399/10/01

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

Scientific title
Comparative study of intravenous injection of pethidine and dexmedetomidine to prevent shivering after cesarean section under spinal anesthesia

Public title
The effect of intravenous injection of pethidine and dexmedetomidine to prevent shivering after cesarean section under spinal anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnancy Elective cesarean section with ASA score 1 and 2 Not addicted to drugs and alcohol based on the patient's statement
Exclusion criteria:
Previous use of painkillers, drugs and alcohol History of severe cardiovascular disease History of kidney and liver diseases Presence of drug allergy Seizures Having fever
Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to meet blindness, the drugs will be prepared by an anesthesiologist before the intervention. In terms of the amount of the drug, all drugs will be reached the same volume (3 ml) using distilled water. These syringes will be coded and placed in the operating room and delivered daily to the anesthesiologist, who will prescribe them without knowing the type of medication. Also, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.
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
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2020-08-02, 1399/05/12
Ethics committee reference number
IR.MUI.MED.REC.1399.361

Health conditions studied

1

Description of health condition studied
Shivering after cesarean section
ICD-10 code
R68.0
ICD-10 code description
Hypothermia, not associated with low environmental temperature

Primary outcomes

1

Description
Central temperature
Timepoint
Every 10 minutes during the operation until leaving the recovery unit
Method of measurement
Tympanic thermometer

2

Description
Peripheral temperature
Timepoint
Every 10 minutes during the operation until leaving the recovery unit
Method of measurement
Axillary thermometer

3

Description
Intensity of shivering
Timepoint
Every 10 minutes during the operation until leaving the recovery unit
Method of measurement
Based on five scores from 0 to 4 so that 0 = no shivering; 1= piloerection or peripheral vasoconstriction but no visible shivering; 2= muscular activity in only one muscle group; 3= muscular activity in more than one muscle group but not generalised shivering; 4= shivering involving the whole body.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: For patients, spinal anesthesia in the lateral decubitus position and at the L3 and L4 levels in the midline is performed after the umbilical cord clamp. The patients are then placed in the supine position with some rotation to the right. Normal saline is administered to patients immediately afterward.
Category
Placebo

2

Description
Intervention group: For patients, spinal anesthesia in the lateral decubitus position and at the L3 and L4 levels in the midline is performed after the umbilical cord clamp. The patients are then placed in the supine position with some rotation to the right. Patients are immediately given 1 µg / kg dexmedetomidine.
Category
Treatment - Drugs

3

Description
Intervention group: For patients, spinal anesthesia in the lateral decubitus position and at the L3 and L4 levels in the midline is performed after the umbilical cord clamp. The patients are then placed in the supine position with some rotation to the right. Patients are immediately given 0.25 mg of pethidine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Behzad Nazemroaya
Street address
Hezar Jarib Street.
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8174673461
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2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source
Isfahan 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
Behzad Nazemroaya

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available