Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the Effectiveness of Prophylaxic Two Different Doses of Dexmedetomidine in Prevention of Shivering During Regional Anesthesia in Cesarean Section

Protocol summary

Study aim
The Survey of Prophylaxic Two Different Doses of Dexmedetomidine in Prevention of Shivering During Regional Anesthesia in Cesarean Section

Design
This study was conducted in parallel ,double-blind,randomized,60 patients who were in the phase 3 trial were designed.

Settings and conduct
Pregnant women referred to Alzahra Hospital and Shahid Beheshti Hospital who underwent spinal anesthesia were divided into three random groups. The first group received 2.5 µg / kg dexmedetomidine The second group received 5 µg / kg dexmedetomidine and the third group received normal saline. Clinical participant, evaluator and analyzer do not understand type of drug and after decoding b, a and c code is decoded by researcher

Participants/Inclusion and exclusion criteria
Enclusion criteria :1-Pregnant women in the age range18-45 2- Anesthesiologists American Society of (ASA)) degree2and3 candidate for cesarean section 3-Patient consent to participate in the study Exclusion criteria:En A history of hypersensivity to alpha adrenergic drug- Liver Patients -Bradycardy history -2nd or 3nd degree AV block Vascular problems- Type 2 diabetes-Hyopvolemia- Taking vasodilator or medications that change the body's central temperature- Drug use

Intervention groups
Informed consent was obtained from the parents of the patients first. After the patients were placed on the operating bed and after connecting standard monitoring including pulse oximeter, barometer, ECG and baseline vital signs, then the intervention group A received2.5 µg / kg dexmedetomidine and Intervention group B received 5 µg / kg dexmedetomidine and the control group received normal saline syringe.

Main outcome variables
Shivering

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N17**
Registration date: **2020-03-19, 1398/12/29**
Registration timing: **retrospective**

Last update: **2020-03-19, 1398/12/29**
Update count: **0**

Registration date
2020-03-19, 1398/12/29

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3212 3543

Email address
behzad_nazem@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-02, 1398/11/13

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Prophylaxic Two Different Doses of Dexmedetomidine in Prevention of Shivering During Regional Anesthesia in Cesarean Section

Public title
The Survey of Prophylaxic Two Different Doses of Dexmedetomidine in Prevention of Shivering During Regional Anesthesia in Cesarean Section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women in the age range18-45 2-Anesthesiologists American Society of (ASA)) degree2and3 candidate for cesarean section Patient consent to participate in the study
Exclusion criteria:
A history of hypersensivity to alpha adrenergic drug Liver Patients Bradycardy history 2nd or 3nd degree AV block Vascular problems Type 2 diabetes Hyopvolemia Taking vasodilator or medications that change the body's central temperature Drug use
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to three groups A, B, C using the Random Allocation computer software
Blinding (investigator's opinion)
Double blinded
Blinding description
The drug and placebo are prepared in one form and in the form of a volume in the syringe by the researcher, and the hemodynamic changes are monitored and recorded, so the attending and the clinical caregiver and the evaluator and data analyser do not understand the type of medication and the investigator deciphers the codes after data analysis.
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
Hezar jarib Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-02-01, 1398/11/12
Ethics committee reference number
IR.MUI.MED.REC.1398.558

Health conditions studied

1

Description of health condition studied
Shivering
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Shivering
Timepoint
Recovery Duration
Method of measurement
Using the Grassi and Mahajan criterion

2

Description
Central temprature
Timepoint
At he base time; after the procedure and then every 15 minutes until discharge of recovery.
Method of measurement
Tympanic thermometer

3

Description

Temperature of Peripheral

Timepoint

At he base time; after the procedure and then every 15 minutes until discharge of recovery.

Method of measurement

Thermometer Skin

4

Description

The level of sedation

Timepoint

At the base time; after the procedure and then every 15 minutes until discharge of recovery.

Method of measurement

Using the Ramsay Sedation Scale

5

Description

Severity of Pain

Timepoint

At of recovery. the base time; after the procedure and then every 15 minutes until discharge

Method of measurement

Using the Visual Analogue Scale

6

Description

Systolic blood pressure

Timepoint

At the base time; after the procedure and then every 15 minutes until discharge of recovery.

Method of measurement

Non invasive blood pressure measurement

7

Description

Diastolic blood pressure

Timepoint

At the base time; after the procedure and then every 15 minutes until discharge of recovery

Method of measurement

Non invasive blood pressure measurement

8

Description

Oxygen saturation

Timepoint

At the base time; after the procedure and then every 15 minutes until discharge of recovery

Method of measurement

Pulse oximetry device

9

Description

Heart Rate

Timepoint

At the base time; after the procedure and then every 15 minutes until discharge of recovery.

Method of measurement

Heart monitoring device

10

Description

Mean Arterial Blood Pressure

Timepoint

At the base time; after the procedure and then every 15 minutes until discharge of recovery.

Method of measurement

Non invasive blood pressure measurement

11

Description

Duration of stay in recovery

Timepoint

From recovery admission to recovery discharge

Method of measurement

Watch or clock

Secondary outcomes

1

Description

Nausea

Timepoint

Duration of stay in recovery

Method of measurement

Questionnaire

2

Description

Vomiting

Timepoint

Duration of stay in recovery

Method of measurement

Questionnaire

3

Description

Itching

Timepoint

Duration of stay in recovery

Method of measurement

Questionnaire

4

Description

Usage of Atropine

Timepoint

From the beginning of the opration to the end of recovery

Method of measurement

Anesthesia Technician Asked About Drug Use

5

Description
Usage of Pethidine
Timepoint
Duration of stay in recovery
Method of measurement
Anesthesia Technician Asked About Drug Use

6

Description
Usage of Ephedrine
Timepoint
From the beginning of the opration to the end of recovery
Method of measurement
Anesthesia Technician Asked About Drug Use

Intervention groups

1

Description
Intervention group A: informed consent from patients first. After patients are placed on operating room bed, standard monitoring including pulse oximeter, barometer, ECG and baseline vital signs Group A = 2.5 µg / kg intravenous dexmedetomidine Is given immediately after induction of anesthesia, and mean arterial blood pressure, heart rate, systolic and diastolic blood pressure, and other variables are considered at the desired times.
Category
Prevention

2

Description
Intervention groupB: informed consent from patients first. After patients are placed on operating room bed, standard monitoring including pulse oximeter, barometer, ECG and baseline vital signs Group A = 5µg / kg intravenous dexmedetomidine Is given immediately after induction of anesthesia, and mean arterial blood pressure, heart rate, systolic and diastolic blood pressure, and other variables are considered at the desired times.
Category
Prevention

3

Description
Control group: informed consent from patients is first obtained. After placing the patients on the operating room bed, standard monitoring including pulse oximeter, barometer, ECG and baseline vital signs are recorded. Intravenous saline is given immediately after induction of anesthesia and moderate arterial blood pressure, heart rate, systolic and diastolic blood pressure, and other variables are considered at the desired time.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra hospital
Full name of responsible person
Behzad Nazemroaya
Street address
Soffeh boulevard, Shahid Keshvari highway
City
Isfahan
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Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
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behzad_nazem@med.mui.ac.ir

2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Behzad Nazemroaya
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West Shahid Motahari Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Shaghyegh Haghjoo
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Postal code
8174673461
Phone

+98 31 3668 0048

Email

research@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

Samira Heydari

Position

Medical student/Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Behzad Nazemroaya

Position

Assistant Professor

Latest degree

Specialist

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Person responsible for updating data

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Position

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Latest degree

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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

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