

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effects of Dexmedetomidine compared with Meperidine on the prevention of postoperative shivering in patients after cesarean section with spinal anesthesia.

Protocol summary

Study aim

Determination and comparison of the effect of Dexmedetomidine with Meperidine in the prevention of postoperative seizures in patients undergoing cesarean section with spinal anesthesia

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 150 patients. For randomization, a randomized block with random samples is used in ten 15-block blocks. In each block, five cards are placed for each group. Then a card is selected from inside the first block. And for the next patient, a card is selected from the same block. By performing each block, five patients were chosen for each group.

Settings and conduct

This study will be done in the field of postoperative seizure prevention in patients undergoing cesarean section with spinal anesthesia at Ali Ibn Abitaleb Hospital in Zahedan. It will be double-blinded. Patients will not be aware of the drug used. An anesthesiologist will prepare the medicine, Who has no role in evaluating the patient. Then it will be delivered to the anesthesiologist. Evaluating nurses won't aware of drug type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All pregnant women between the ages of 18 and 45 who have had a cesarean section using spinal anesthesia and are physically classified in I and II classes of the American Society of Anesthesiologists. Exclusion criteria: History of allergy to the drugs studied, Addiction, Taking Alpha-antagonist drugs, Altered thyroid function, Coronary artery insufficiency and high blood pressure, Asthma and Respiratory failure, Liver or kidney failure, History of seizures.

Intervention groups

Dexmedetomidine group Meperidine group Placebo group

Main outcome variables

Postoperative shivering

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190603043799N1**

Registration date: **2020-08-03, 1399/05/13**

Registration timing: **prospective**

Last update: **2020-08-03, 1399/05/13**

Update count: **0**

Registration date

2020-08-03, 1399/05/13

Registrant information

Name

Sufia Ahrari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3322 7108

Email address

sa_ahrari186@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Dexmedetomidine compared with Meperidine on the prevention of postoperative shivering in patients after cesarean section with spinal anesthesia.

Public title

The effects of Dexmedetomidine compared with Meperidine on the prevention of postoperative shivering.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All pregnant women are 18 to 45 years old Perform cesarean section using spinal anesthesia Physically, they are in the first and second class of the American Society of Anesthesiologists

Exclusion criteria:

History of allergy to the drugs studied Addiction Taking Alpha-antagonist drugs Altered thyroid function Coronary artery insufficiency and high blood pressure Asthma and Respiratory failure Liver or kidney failure History of seizures History of nausea and vomiting in a previous surgery

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocks containing three random digits cards, each of which represents three groups, will be prepared and placed in ten blocks of 15 using the random method blocked by the sample. Then, the participants that have the conditions for entering the study are selected from one of the blocks, respectively, from one side of the card block, and according to it, they are in one of the three groups receiving Dexmedetomidine and Meperidine (test group) and Control (placebo).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients won't be aware of the used medication. An anesthesiologist will prepare the drug, Who has no role in evaluating the patient. Then it will deliver to the anesthesiologist.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan university of medical sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

4318198167

Approval date

2019-07-12, 1398/04/21

Ethics committee reference number

IR.ZAUMS.REC.1398.267

Health conditions studied**1****Description of health condition studied**

Chills

ICD-10 code

R68.83

ICD-10 code description

Chills (without fever)

Primary outcomes**1****Description**

Cesarean section postoperative shivering with spinal anesthesia

Timepoint

The presence of Shivering will evaluate at 15, 30, 45, and 60 minutes after medicine injection.

Method of measurement

Patient evaluation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Receiving Dexmedetomidine at a dose of 0.5 micrograms per kilogram

Category

Treatment - Drugs

2

Description

Intervention group: Receiving Meperidine at a dose of 0.4 milligrams per kilogram

Category

Treatment - Drugs

3

Description

Control group: Receiving 10 millilitre of sodium chloride 0.9%

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

ali ibn abi talib hospital

Full name of responsible person

Sofia Ahrari

Street address

ali ibn abi talib hospital, Salamat Blvd., Khalij fars highway.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Noormohammad Bakhshani

Street address

Zahedan university of medical sciences ,Dr. Hesabi Square, Khalij fars highway.

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Email

zaums.research@gmail.com

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Sofia Ahrari

Position

Resident in anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Web page address

Person responsible for scientific inquiries

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Mehdi Heydari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

Resident in anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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