

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of Local Subcutaneous Infiltration with Ropivacaine Alone or Two Different Doses of Dexmedetomidine plus Ropivacaine for Postoperative Pain After Cesarean Section Under Spinal Anesthesia.

Protocol summary

Study aim

Determining and comparing the average pain intensity based on VAS at baseline, every 15 minutes during recovery, at 2, 4, 6, 12, 24 hours after entering the ward in the 3 study groups Determining and comparing the average time of the first request for additional Analgesic in the 3 study groups Determining and comparing the average dose of additional analgesics in the 3 studied groups Determining and comparing the average degree of patient satisfaction based on VAS in the 3 studied groups Determining and comparing the average number of people in need of additional Analgesic in the 3 studied groups

Design

A clinical trial with a control group with 3 parallel groups, three blind strains, randomized, phase 3 on 90 patients, Random Allocation software was used

Settings and conduct

The current study is a three-way blind controlled RCT(patients, people who collect information, and someone who analyzes the information) that will be conducted in 1401-1402 at Beheshti medical Center. standard monitoring is established. The two drugs ropivacaine and the combination of ropivacaine and dexmedetomidine will be prepared by the nurse in similar syringes and will be labeled with three codes A, B, and C. They are given to an anesthesiologist daily for injection.

Participants/Inclusion and exclusion criteria

candidates for cesarean surgery (for the first time) undergoing cesarean surgery under spinal anesthesia and with ASA I&II are included in the study, and people with allergy to drugs or other underlying diseases are not included.

Intervention groups

At the end of the operation, before closing the wound incision, patients will be injected with ropivacaine or

ropivacaine with dexmedetomidine in two different doses of 1 and 2 mg/kg according to the 3 study groups.

Main outcome variables

Pain intensity based on VAS, occurrence of complications, need for Analgesic and the first time to receive Analgesic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221122056579N1**

Registration date: **2022-12-04, 1401/09/13**

Registration timing: **prospective**

Last update: **2022-12-04, 1401/09/13**

Update count: **0**

Registration date

2022-12-04, 1401/09/13

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Local Subcutaneous Infiltration with Ropivacaine Alone or Two Different Doses of Dexmedetomidine plus Ropivacaine for Postoperative Pain After Cesarean Section Under Spinal Anesthesia.

Public title
Comparison the Effect of Adding Two Different Doses of Dexmedetomidine to Ropivacaine on Pain After Cesarean Section

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients who are candidates for cesarean surgery (for the first time) Performing cesarean surgery under spinal anesthesia ASA I&II (American society of anesthesiologists)
Exclusion criteria:
 Patients with a History of Drug Allergy (Dexmedetomidine And Ropivacaine) Patients with a History of Tobacco and Opioid Addiction Patients with Psychological Problems Obese Patients Weighing More Than 100 kg Patients with Inability to Express Pain Score Suffering from Intracranial Hypertension Twin Pregnancy and Above Previous Abdominal and Pelvic Surgeries Uncontrollable Underlying Disease (ASA3 and higher)

Age
From **15 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The random division of eligible people into three groups is done using a table of random numbers. Tables of random numbers are prepared by computers that arrange numbers randomly. These tables have random numbers in both row and column directions, which usually reach 99 rows and columns, and the numbers of the rows and columns are in blocks of five digits next to each other and in a separated form to facilitate its use. To use the table of random numbers, the researcher

must first find out the exact number of people in the society and give them a code in order. In this study, 90 people (total samples) should be divided into 3 groups of 30 people. Therefore, to each of the 90 people, two-digit codes such as 01, 02, 03, ..., 11, 12, 89, 90 is given. To select sample people from the table, the researcher randomly starts from a point of the table in the row or column direction. She can choose the point by closing his eyes and placing his finger or pen tip on the table. Movement in the direction of row or column does not differ and this work is related to the researcher's desire. But due to the two-digit codes, she must choose the same number of digits in the direction of the row or column. After this, numbers control the route. Willingly or not, she will come across two types of numbers, one of which is smaller than 90 and the other is larger than 90. She should pay attention and choose only the smaller numbers. The selected number is actually the code of an individual from the community that is selected as a sample. This work should continue until a small number can be selected for the number of sample people. After completing the sample volume, the first group is determined. To select the second group, after removing the people of the first group from the total of 90 people, this time she does the same thing considering 60 people and 30 people are selected from them. In this way, the remaining 60 people form the third group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding method: the person who collects the data, the person who performs the statistical analysis, and the patients, do not know about the study groups. In order to comply with the conditions of blinding, the two drugs ropivacaine and the combination of ropivacaine and dexmedetomidine in two different doses of 1 and 2 mg/kg were prepared by the operating room nurse in similar syringes with the same size and labeled with three codes A, B, C before surgery. They will be placed and daily provided to an anesthetist and he will make the relevant prescription without knowing the type of intervention. In addition, the evaluator who is responsible for collecting information and the patient will not know the type of intervention in each group. The statistical analyst will not know the type of the two groups under study. In this way, the condition of being three-blind will be established.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Isfahan University of Medical Sciences

Street address

No. 18, Safabakhsh Alley, Rajaei St

City

Najafabad

Province

Isfahan

Postal code

8513675711

Approval date

2022-11-22, 1401/09/01

Ethics committee reference number

IR.MUI.MED.REC.1401.307

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

Postoperative Pain after Cesarean Section, The effect of ropivacaine and dexmedetomidine drugs

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain after cesarean section based on Visual Analogue Scale

Timepoint

Pain at baseline (before spinal anesthesia) and then every 15 minutes during recovery and after that at 2, 4, 6, 12, 24 hours after surgery in the ward

Method of measurement

Visual Analogue Scale, It is evaluated based on a score from 0 (no pain) to 10 (severe pain).

Secondary outcomes**1****Description**

The amount of additional analgesic

Timepoint

If the patient's VAS is more than 4 cm, diclofenac sodium suppository 100 mg is used to relieve pain.

Method of measurement

The number of diclofenac sodium suppositories 100 mg

2**Description**

The first time to receive analgesics

Timepoint

If the patient's VAS is more than 4 cm, diclofenac sodium suppository 100 mg is used to relieve pain.

Method of measurement

Number of minutes after surgery

3**Description**

- The incidence of side effects include: nausea and vomiting, chills, hallucinations, hypotension (<30% of baseline), bradycardia (<60), hypertension and tachycardia (increase of more than 30% compared to baseline), Respiratory depression (< 10 times per minute)

Timepoint

After recovery until discharge

Method of measurement

has/doesn't have

4**Description**

Patient satisfaction based on VAS

Timepoint

in hours 2, 4, 6, 12, 24 after entering the ward

Method of measurement

Visual Analogue Scale

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

The first intervention group, In this group, at the end of the operation, before closing the wound, dexmedetomidine with a dose of 1 microgram/kg is injected into the patient in the form of subcutaneous infiltration with 0.5% ropivacaine at the rate of 3 mg/kg, which reaches a volume of 40 cc.

Category

Treatment - Drugs

2**Description**

The second intervention group, In this group, at the end of the operation, before closing the wound, dexmedetomidine with a dose of 2 microgram/kg is injected into the patient in the form of subcutaneous infiltration with 0.5% ropivacaine at the rate of 3 mg/kg, which reaches a volume of 40 cc.

Category

Treatment - Drugs

3**Description**

Control group, In this group, at the end of the operation, before closing the wound, ropivacaine 0.5% is injected to the patient at the rate of 3 mg/kg alone in a volume of 40 cc.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Atefeh Ghosouri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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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

Atefeh Ghosouri

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

Yes - There is 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

Title and more details about the data/document

The results of this study can be presented as a successful and satisfactory treatment protocol if dexmedetomidine and ropivacaine are effectively shown and the effect of its two different doses is investigated.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Students and people interested in this field

Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

By contacting the main executive of the project with an email address, atefehghosouri@med.mui.ac.ir

What processes are involved for a request to access data/document

After contacting the main project manager and her approval, the information will be sent to the person

Comments