

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the effect of ropivacaine - Dexedomidine and ropivacaine - fentanyl on reduction of acute pain after cesarean section by epidural

Protocol summary

Study aim

Comparison of the effect of ropivacaine - Dexedomidine and ropivacaine - fentanyl on reduction of acute pain after cesarean section by epidural

Design

After obtaining permission from the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences and approving the Imam Khomeini Hospital Pain Research Center, 80 patients (first and second abdomen) between the ages of 18 and 30 with (BMI = 20-25) candidate for surgery Elective cesarean section with ASA class II and I as input criteria is randomly divided into groups A and B. All patients will be provided written informed consent to participate in the project. group A, ropivacaine (120 mg / kg) - dexmedetomidine (1 microgram / kg) group B, ropivacaine (120 mg / kg) - fentanyl (20 microgram / kg) they receive.

Settings and conduct

The study is a double blind clinical trial. The study site is Imam Khomeini Hospital in Ahvaz.

Participants/Inclusion and exclusion criteria

Eighty patients (first and second abdomen) between 18-30 years who are candidates for elective cesarean section with ASA class I and II are considered as input factors. As the output of the study, preterm labor (less than 37 weeks) asthma, cardiovascular disease, preeclampsia, history of seizures, conversion to spinal anesthesia to complete anesthesia, history of chronic pain such as low back pain and fibromyalgia, as well as opioid use and mood and psychologic disorders , were considered

Intervention groups

Group 1: Ropivacaine - Dexmedicomidine Group 2: Ropivacaine - Fentanyl

Main outcome variables

ropivacaine fentanyl dexamethidine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191026045246N1**

Registration date: **2020-02-27, 1398/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-27, 1398/12/08**

Update count: **0**

Registration date

2020-02-27, 1398/12/08

Registrant information

Name

Anahita Kalantari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8414

Email address

kalantar-h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-07, 1398/11/18

Expected recruitment end date

2020-09-17, 1399/06/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ropivacaine -
Dexedomidine and ropivacaine - fentanyl on reduction
of acute pain after cesarean section by epidural

Public title

Comparison of the effect of ropivacaine -
Dexedomidine on reduction of acute pain after
cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Elective Cesarean section with Class I and II ASA

Exclusion criteria:

Preterm labor (less than 37 weeks) asthma
cardiovascular disease preeclampsia history of seizures,
becoming spinal anesthesia to complete anesthesia
history of chronic pain such as low back pain and
fibromyalgia, opioid use mood and Psychological
disorders

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

2-3

Groups that have been masked

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

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, block

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, principal investigator, especially in trials
initiated by academic researchers, health care personnel
(physicians, nurses, physiotherapists, etc.) responsible
for patient care, data collection officers, and those who
evaluate the outcome and, to a lesser extent, data safety
and monitoring committee are blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee Acts of Ahvaz Jundishapur
University of Medical Science

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2019-10-11, 1398/07/19

Ethics committee reference number

IR.AJUMS.REC.1398.517

Health conditions studied

1

Description of health condition studied

cesarean section

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

2, 4, 8, 12 and 24 hours after surgery

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

The patient's first time complaining of pain

Timepoint

The first time a patient feels pain after surgery

Method of measurement

Minutes

2

Description

The amount of analgesic drug

Timepoint

The onset of pain

Method of measurement

Mg / kg

3

Description

rupivacaine

Timepoint

Before surgery

Method of measurement

Mg / kg

4

Description

Dexedodomidine

Timepoint

Before surgery

Method of measurement

Mg / kg

5

Description

fentanyl

Timepoint

Before surgery

Method of measurement

Mg / kg

Intervention groups

1

Description

Intervention group: rupivacaine - Dexedodomidine

Category

Treatment - Drugs

2

Description

Intervention group: rupivacaine - fentanyl

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ahvaz

Full name of responsible person

Anahita Kalantari

Street address

Azadegan Street - Imam Khomeini hospital of Ahwaz

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6193673111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Akhondzadeh

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Akhondzadeh

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)

Yes - There is 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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data can be shared after unidentifiable people

When the data will become available and for how long

Start access period 6 months after publishing results "

To whom data/document is available

The data for this study will only be available to researchers working in academia

Under which criteria data/document could be used

There is no specific requirement

From where data/document is obtainable

Reza Akhondzadeh rezaakh@hotmail.com

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

3 months

Comments