

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the additive effect of dexmedetomidine and neostigmine to bupivacaine on pain intensity after cesarean section with spinal anesthesia

Protocol summary

Study aim

The effect of dexmedetomidine and neostigmine on reducing postoperative pain by cesarean section with spinal anesthesia

Design

Randomization is based on block randomization, which is double-blind. The sample size is calculated in each group of 51 people. Patient. Excel software rand function was used for randomization.

Settings and conduct

This study is a randomized clinical trial study that will be performed at Imam Khomeini Hospital in Sari, Mazandaran Province, on women who are candidates for cesarean delivery and are between 18 and 50 years old.

Participants/Inclusion and exclusion criteria

Women who have had a cesarean delivery and are between 18 and 50 years old.

Intervention groups

It consisted of two groups of 51 women who were candidates for cesarean section and efficacy of dexmedetomidine and neostigmine that added to bupivacaine for spinal anesthesia has compared

Main outcome variables

Pain based on visual analog scale criteria; Calming based on Ramsey criteria; Immobility according to Broming criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161126031095N2**

Registration date: **2021-07-13, 1400/04/22**

Registration timing: **retrospective**

Last update: **2021-07-13, 1400/04/22**

Update count: **0**

Registration date

2021-07-13, 1400/04/22

Registrant information

Name

Alieh Zamani Kiasari

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 11 3335 5080

Email address

azamani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

2020-12-05, 1399/09/15

Actual recruitment end date

2021-03-02, 1399/12/12

Trial completion date

2021-04-19, 1400/01/30

Scientific title

Comparison of the additive effect of dexmedetomidine and neostigmine to bupivacaine on pain intensity after cesarean section with spinal anesthesia

Public title

Comparison of the additive effect of dexmedetomidine and neostigmine to bupivacaine on pain intensity after cesarean section with spinal anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women who have had a cesarean delivery

Exclusion criteria:

Patients who have refused to participate Drug addiction
Have underlying diseases (moderate or severe heart, kidney, lung or nerve disease, significant scoliosis, kyphosis, obesity or blood clotting disease) Patients with a height of less than 130 cm or aBody mass Index (BMI) of more than 35

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **110**

Actual sample size reached: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by randomized block method with various block sizes (multiples of 2). The unit is individual and is made by statistical software and delivered in a sealed envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The facilitator, the senior assistant performing spinal anesthesia, and the anesthetist present at the patient's bedside, as well as the first-year assistant filling out research forms were kept blind for each patient' administered drugs. The drugs were the same color and volume in the same syringes that could not be differentiated by the above individuals

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Khomeini Hospital of Sari - Mazandaran University of Medical Sciences

Street address

Office Building Ethics Committee of Imam Khomeini Hospital Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

48166-33131

Approval date

2020-11-25, 1399/09/05

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1399.062

Health conditions studied

1

Description of health condition studied

Other acute postprocedural pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Pain after cesarean section

Timepoint

Hours 0, 2, 4, 8 and 12

Method of measurement

According to the Visual Analogue Scale criteria

Secondary outcomes

1

Description

Sedation

Timepoint

0,2,4,8,12

Method of measurement

Ramsay Criteria

2

Description

Immobilization

Timepoint

0,2,4,8,12

Method of measurement

Bromage scale

3

Description

Moderate arterial blood pressure

Timepoint

0,2,4,8,12

Method of measurement

Checklist

4

Description

Oxygen saturation

Timepoint

0,2,4,8,12

Method of measurement

pulse oximetry

5

Description

Apgar score

Timepoint

0,2,4,8,12

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group1: 1 microgram of dexmedetomidine is equivalent to a volume of 0.5 ml plus 2.5 ml of 0.5% bupivacaine. As a result, the total injection volume in each sample is 3 ml, which have the same color and shape. No. 25 and is performed from the lumbar intervertebral space in the cerebrospinal fluid

Category

Treatment - Drugs

2

Description

Intervention group2:10 micrograms of neostigmine is equivalent to a volume of 0.5 ml plus 2.5 ml of 0.5% bupivacaine. As a result, the total injection volume in each sample is 3 ml, which have the same color and shape. Spinal cord No. 25 and is performed from the lumbar intervertebral space in the cerebrospinal fluid

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

Alieh Zamani Kiasari

Street address

Imam Khomeini Hospital, Amir Mazandarani
Boulevard, Sari

City

Sari

Province

Mazandaran

Postal code

48166-33131

Phone

+98 11 3336 1700

Fax

+98 11 3336 1630

Email

aliehzamani@yahoo.com

Web page address

<https://www.mazums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saedi

Street address

Moalem Ave

City

Sari

Province

Mazandaran

Postal code

48157-33971

Phone

+98 11 3325 7230

Fax

+98 11 3325 7230

Email

m.saedi@mazums.ac.ir

Web page address

https://www.mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Iman Asdaghi Jahromi

Position

Anesthesia Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Clinical Research Development Center, Imam Khomeini Hospital, Amir Mazandarani Boulevard

City

Sari

Province

Mazandaran

Postal code

48166-33131

Phone

+98 11 3335 5080

Fax

+98 11 3335 5080

Email

Iman.asdaghi@gmail.com

Web page address

<https://www.mazums.ac.ir>

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Alieh Zamani Kiasari

Position

Assistance professor of Anesthesiology and Intensive Care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Phone

+98 11 3335 5080

Fax

+98 11 3335 5080

Email

aliehzamani@yahoo.com

Web page address

<https://www.mazums.ac.ir>

Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Alieh Zamani Kiasari

Position

Associate Professor of Anesthesiology and Vegetative Care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Clinical Research Development Center, Imam Khomeini Hospital, Amir Mazandarani Boulevard

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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