

# 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

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**Province**

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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**

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**Web page address**

[https://www.mazums.ac.ir](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

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**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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**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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**Email****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