

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Comparing the effect of adding dexmedetomidine and low dose of naloxone to morphine on the pain-free period of post-operative analgesia after spinal anesthesia in cesarean section

#### Protocol summary

##### Study aim

Comparison of the effects of morphine along with low dose naloxone and dexmedetomidine during analgesia after cesarean section under spinal anesthesia

##### Design

Clinical trial with a control group, with parallel groups, doubleblind, randomized, phase 3 on 90 patients. The rand function of Excel software was used for randomization.

##### Settings and conduct

This study is a double-blind randomized clinical trial that was conducted in Imam Khomeini Sari Educational-Therapeutic Hospital in Mazandaran province on women who are candidates for elective cesarean delivery between 18 and 50 years old who are the first and second gravid. will be executed. Patients will be randomly divided into three groups A, B and C based on a computerized list which is a statistic and does not know about the people present in the treatment groups. 2) and the receiving patient are not aware of the content of the injected drug.

##### Participants/Inclusion and exclusion criteria

Entry conditions: women aged 18 to 50 years, elective cesarean delivery, first and second gravid  
Exclusion criteria: patient refusal to participate in the study, failure to create the required level of anesthesia and conversion of spinal anesthesia to general, history of drug addiction, history of sensitivity to any of the drugs used in this research, history of known heart disease vascular, liver, kidney and blood coagulation problems and asthma, scoliosis or kyphosis or morbid obesity, height less than 130 cm and BMI higher than 35

##### Intervention groups

Intervention group: 100 micrograms of morphine with 2.5 cc of bupivacaine 0.5% plus a low dose of 2 micrograms of naloxone. Intervention group: 1 microgram (dexmedetomidine) with 2.5 cc bupivacaine 0.5% Control

group: 2.5 cc of bupivacaine 0.5% will be injected intrathecally

##### Main outcome variables

Pain intensity, sedation scores

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161126031095N5**

Registration date: **2023-08-10, 1402/05/19**

Registration timing: **prospective**

Last update: **2023-08-10, 1402/05/19**

Update count: **0**

##### Registration date

2023-08-10, 1402/05/19

##### 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

2023-08-12, 1402/05/21

##### Expected recruitment end date

2023-10-13, 1402/07/21

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effect of adding dexmedetomidine and low dose of naloxone to morphine on the pain-free period of post-operative analgesia after spinal anesthesia in cesarean section

**Public title**

Comparing the effect of adding dexmedetomidine and low dose of naloxone to morphine on the pain-free period of post-operative analgesia after spinal anesthesia in cesarean section

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women aged 18 to 50 years Elective cesarean birth for first and second gravid

**Exclusion criteria:**

Patient refusal to participate in the study Failure to create the required level of anesthesia and turning spinal anesthesia into general History of drug addiction History of allergy to any of the drugs used in this research History of known cardiovascular, liver, kidney disease and blood coagulation problems and asthma Scoliosis or kyphosis or morbid obesity Height less than 130 cm and BMI greater than 35 Ketamine or narcotic injection to treat shivering in the second line

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

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

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization will be divided based on the basic variables: age and gestational age. The participants will be randomly divided into 3 groups: 1) 100 micrograms of morphine with 2.5 cc of bupivacaine 0.5% plus a low dose of 2 micrograms of naloxone 2) 1 microgram of dexmedetomidine with 2.5 cc of bupivacaine 0.5% 3) 2.5cc bupivacaine 0.5% All syringes containing medicine are transparent and in the same volume and different concentrations which are delivered in sealed envelopes, the patients are divided into three groups A, B and C

based on the computer list which is a statistic, there is no information about the people present in the treatment groups the people present in the treatment groups

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All the syringes containing drugs are transparent and in the same volume and different concentrations, only the project manager (senior anesthesiology assistant) administers morphine, naloxone and dexmedetomidine drugs with a certain effective dose to add to bupivacaine to the second year anesthesiology assistants. to perform spinal) delivers. The injecting doctor (second-year anesthesiology resident) and the receiving patient are not aware of the content of the injected drug.

**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 Educational and Medical Hospital (RA) Sari - Mazandaran University

**Street address**

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

**City**

Sari

**Province**

Mazandaran

**Postal code**

48166-33131

**Approval date**

2023-02-01, 1401/11/12

**Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.1402.013

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

Intensity of pain

**ICD-10 code**

G89.18

**ICD-10 code description**

Other acute postprocedural pain

**Primary outcomes**

|                                    |                                          |
|------------------------------------|------------------------------------------|
| <b><u>1</u></b>                    | Alieh Zamani Kiasari                     |
| <b>Description</b>                 | <b>Street address</b>                    |
| Severity of patients' pain         | Imam Khomeini Hospital, Amir Mazandarani |
| <b>Timepoint</b>                   | Boulevard, Sari                          |
| In hours 2, 4, 8, 12 after surgery | <b>City</b>                              |
| <b>Method of measurement</b>       | Sari                                     |
| Visual Analogue Scale              | <b>Province</b>                          |
|                                    | Mazandaran                               |
|                                    | <b>Postal code</b>                       |
|                                    | 48166-33131                              |
|                                    | <b>Phone</b>                             |
|                                    | +98 11 3336 1700                         |
|                                    | <b>Fax</b>                               |
|                                    | +98 11 3336 1700                         |
|                                    | <b>Email</b>                             |
|                                    | aliehzamani@yahoo.com                    |
|                                    | <b>Web page address</b>                  |
|                                    | https://www.mazums.ac.ir/                |

## Secondary outcomes

|                                      |
|--------------------------------------|
| <b><u>1</u></b>                      |
| <b>Description</b>                   |
| Sedation score                       |
| <b>Timepoint</b>                     |
| In hours 2, 4, 8, 12 after surgery   |
| <b>Method of measurement</b>         |
| Reverse Observer Assessment Scale of |
| Consciousness/Sedation               |

## Intervention groups

|                                                                                                                                                                                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b><u>1</u></b>                                                                                                                                                                                                                                                                        |
| <b>Description</b>                                                                                                                                                                                                                                                                     |
| Intervention group: 100 micrograms of morphine (manufactured by Abu Rehan Company) with 2.5 cc of bupivacaine 0.5% (manufactured by Abu Rehan Pharmaceuticals) plus a low dose of 2 micrograms of naloxone (manufactured by Drug Manufacturing Company) as a single dose by injection. |
| <b>Category</b>                                                                                                                                                                                                                                                                        |
| Treatment - Surgery                                                                                                                                                                                                                                                                    |
| <b><u>2</u></b>                                                                                                                                                                                                                                                                        |
| <b>Description</b>                                                                                                                                                                                                                                                                     |
| Intervention group:1 microgram of dexmedetomidine (manufactured by Elixir Pharmaceutical Company) with 2.5 cc of bupivacaine 0.5% (manufactured by Abu Rahian Pharmaceutical Company) as a single dose by injection                                                                    |
| <b>Category</b>                                                                                                                                                                                                                                                                        |
| Treatment - Surgery                                                                                                                                                                                                                                                                    |
| <b><u>3</u></b>                                                                                                                                                                                                                                                                        |
| <b>Description</b>                                                                                                                                                                                                                                                                     |
| 2.5 cc bupivacaine 0.5% (manufactured by Abu Rahian Pharmaceuticals) intrathecally as a single dose by injection                                                                                                                                                                       |
| <b>Category</b>                                                                                                                                                                                                                                                                        |
| Treatment - Surgery                                                                                                                                                                                                                                                                    |

## Recruitment centers

|                                        |
|----------------------------------------|
| <b><u>1</u></b>                        |
| <b>Recruitment center</b>              |
| <b>Name of recruitment center</b>      |
| Imam Khomeini Hospital, Sari           |
| <b>Full name of responsible person</b> |

## Sponsors / Funding sources

|                                                                       |
|-----------------------------------------------------------------------|
| <b><u>1</u></b>                                                       |
| <b>Sponsor</b>                                                        |
| <b>Name of organization / entity</b>                                  |
| Mazandaran University of Medical Sciences                             |
| <b>Full name of responsible person</b>                                |
| Majid Saedi                                                           |
| <b>Street address</b>                                                 |
| Moalem Ave                                                            |
| <b>City</b>                                                           |
| Sari                                                                  |
| <b>Province</b>                                                       |
| Mazandaran                                                            |
| <b>Postal code</b>                                                    |
| 48157-33971                                                           |
| <b>Phone</b>                                                          |
| +98 11 3325 7230                                                      |
| <b>Fax</b>                                                            |
| +98 11 3325 7230                                                      |
| <b>Email</b>                                                          |
| m.saedi@mazums.ac.ir                                                  |
| <b>Web page address</b>                                               |
| https://www.mazums.ac.ir                                              |
| <b>Grant name</b>                                                     |
| <b>Grant code / Reference number</b>                                  |
| <b>Is the source of funding the same sponsor organization/entity?</b> |
| Yes                                                                   |
| <b>Title of funding source</b>                                        |
| Mazandaran University of Medical Sciences                             |
| <b>Proportion provided by this source</b>                             |
| 100                                                                   |
| <b>Public or private sector</b>                                       |
| Public                                                                |
| <b>Domestic or foreign origin</b>                                     |
| Domestic                                                              |
| <b>Category of foreign source of funding</b>                          |
| empty                                                                 |
| <b>Country of origin</b>                                              |
| <b>Type of organization providing the funding</b>                     |
| Academic                                                              |

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Iran 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

**Street address**

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

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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**

Associate Professor of Anesthesiology and Vegetative Care

**Latest degree**

Specialist

**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

**Street address**

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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