

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

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

Secondary outcomes

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

Intervention groups

<u>1</u>
Description
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.
Category
Treatment - Surgery
<u>2</u>
Description
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
Category
Treatment - Surgery
<u>3</u>
Description
2.5 cc bupivacaine 0.5% (manufactured by Abu Rahian Pharmaceuticals) intrathecally as a single dose by injection
Category
Treatment - Surgery

Recruitment centers

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

Sponsors / Funding sources

<u>1</u>
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

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

City

Sari

Province

Mazandaran

Postal code

48166-33131

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 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

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

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

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

+98 911 151 7833

Email

aliehzamani@yahoo.com

Web page address

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

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