

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of dexmedetomidine and lower dose of neostigmine in pain relief after cesarean section with spinal anesthesia

Protocol summary

Study aim

Comparison of the effect of dexmedetomidine and lower dose of neostigmine in pain relief after cesarean section with spinal anesthesia

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 102 patients. The rand function of Excel software was used for randomization.

Settings and conduct

This study is a randomized clinical trial study that will be conducted at Imam Khomeini Sari Educational-Therapeutic Hospital in Mazandaran province on women who are candidates for elective cesarean delivery and are between 18 and 50 years old. These women will be selected for the study based on the body status I and II of the American Society of Anesthesiology (ASA).

Participants/Inclusion and exclusion criteria

Entry criteria: women who had an elective cesarean delivery and are between 18 and 50 years old. Exclusion criteria: patients who refused to participate, or after spinal anesthesia, the required sensory level was not established and then underwent general anesthesia, as well as patients with a history of allergy to any of the drugs used in this research, a history of drug addiction. And moderate or severe heart, kidney, lung or nervous diseases, significant scoliosis or kyphosis, excessive obesity or blood coagulation disease will be excluded from the study. Patients with height less than 130 cm or BMI more than 35 are excluded from the study.

Intervention groups

Group (1): 50 micrograms of neostigmine plus 2.5 cc of bupivacaine 0.5% Group 2: 1 microgram of dexmedetomidine plus 2.5 cc of bupivacaine 0.5%

Main outcome variables

Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210904052371N4**

Registration date: **2023-08-22, 1402/05/31**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-22, 1402/05/31**

Update count: **0**

Registration date

2023-08-22, 1402/05/31

Registrant information

Name

Goli Aezi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3311 9875

Email address

gaezi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-17, 1402/05/26

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of dexmedetomidine and lower dose of neostigmine in pain relief after cesarean section with spinal anesthesia

Public title

Comparison of the effect of dexmedetomidine and lower dose of neostigmine in pain relief after cesarean section with spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women who had an elective cesarean delivery Women who are between 18 and 50 years old.

Exclusion criteria:

Patients who refused to participate, or after spinal anesthesia, the required sensory level was not established and were then subjected to general anesthesia. Patients with a history of allergy to any of the drugs used in this research History of drug addiction Moderate or severe heart, kidney, lung or nervous diseases Significant scoliosis or kyphosis Excessive obesity Blood coagulation disease Patients with height less than 130 cm or BMI more than 35

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: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients after choosing and obtaining informed consent to participate in the study after explaining the steps of conducting the research by randomization block method (with various block sizes (multiples of 2)) by computer and online (using the website www.random.org/integres) patients were randomly divided into two groups A and B, each of which had its own code. These codes were written on the final envelope in which the patient group was specified. Without knowing these codes, the research colleagues placed the patients in one of the two groups by selecting each envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be done in the following way: the project manager (anesthetist) will deliver neostigmine and dexmedetomidine drugs with specific dosage to be added to bupivacaine to the second year anesthesiology assistants (to perform spinal anesthesia).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Imam (RA) Sari Educational and Medical Hospital - Mazandaran University of Medical Sciences (Research)

Street address

Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

33131 - 48166

Approval date

2023-12-05, 1402/09/14

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1402.053

Health conditions studied

1

Description of health condition studied

Severity of pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

intensity of pain

Timepoint

0, 2, 4, 8 and 12 hours

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Sedation rate

Timepoint

Hours 0, 2, 4, 8 and 12

Method of measurement

Using the Ramsay scale

Intervention groups

1

Description

Intervention group: 50 micrograms of neostigmine (manufactured by Subhan Pharmaceutical Company, Iran) plus 2.5 cc bupivacaine (manufactured by Elixir Pharmaceutical Company, Iran) 5% will be injected as a single dose in order to evaluate clinical outcomes.

Category

Treatment - Drugs

2

Description

Intervention group: 1 microgram of dexmedetomidine (manufactured by Daro Farah Pharmaceutical Company, Iran) plus 2.5 cc of bupivacaine (manufactured by Elixir Pharmaceutical Company, Iran) 5% will be injected as a single dose in order to evaluate clinical outcomes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Goli Azzi

Street address

Amir Mazandarani St. Imam Khomeini Hospital

City

Sari

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48166-33131

Phone

+98 11 3336 1700

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Email

Gaezi@mazums.ac.ir

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

Joybar intersection of Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

48157-33971

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Fax

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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

Goli Azzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Amir Mazandarani St. Imam Khomeini Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Goli Azzi

Position
Associate professor

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Person responsible for updating data

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Web page 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