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 (Researc
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
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Web page address
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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
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Province
Mazandaran
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48157-33971
Phone
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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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Person responsible for updating data

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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