

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the effect of adding dexmedetomidine with dexamethasone to bupivacaine in abdominal transverse block on pain intensity after laparoscopic cholecystectomy

Protocol summary

Study aim

Comparison of the effect of adding dexmedetomidine with dexamethasone to bupivacaine in transverse abdominal plane block on pain intensity, hemodynamic parameters and other outcomes after laparoscopic cholecystectomy surgery.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 111 patients. Excel software was used for Blocked Randomization.

Settings and conduct

It will be carried out in the Imam Khomeini Educational-Therapeutic Hospital of Sari in Mazandaran province. In this study, the patient and the final evaluator will not know about the allocation method (double-blind).

Participants/Inclusion and exclusion criteria

Physical status of ASA class I and II, age between 18-65 years and exclusion conditions: patient refusal to participate. Neuromuscular diseases (for example, myopathy, myasthenia gravis). Hematological diseases, bleeding or coagulation disorders. Local skin infection and Sepsis at the site of the block. Known hypersensitivity to the study drugs. Morbid obesity (BMI > 35), sleep apnea or any other sleep disorder, history of alcoholism or drug addiction, any uncompensated systemic disease, other mental or emotional problems.

Intervention groups

Control group = patients will receive 17 ml of 0.25% bupivacaine + 3 ml of 0.9% saline in a total volume of 20 ml per side Dexamethasone group: patients will receive 17 mL of 0.25% bupivacaine + dexamethasone (4 mg) diluted in 3 mL of 0.9% saline in a total volume of 20 mL per side. Dexmedetomidine group = patients will receive 17 ml bupivacaine 0.25% + dexmedetomidine (1 µg/kg) diluted in 3 ml saline 0.9% in a total volume of 20 ml on each side.

Main outcome variables

Pain intensity, nausea, sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161126031095N4**

Registration date: **2023-06-24, 1402/04/03**

Registration timing: **prospective**

Last update: **2023-06-24, 1402/04/03**

Update count: **0**

Registration date

2023-06-24, 1402/04/03

Registrant information

Name

Alieh Zamani Kiasari

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

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azamani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-26, 1402/04/05

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of adding dexmedetomidine with dexamethasone to bupivacaine in abdominal transverse block on pain intensity after laparoscopic cholecystectomy

Public title
Comparison of the effect of adding dexmedetomidine with dexamethasone to bupivacaine in abdominal transverse block on pain intensity after laparoscopic cholecystectomy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
ASA class I and II physical condition Age between 18-65 years
Exclusion criteria:
Patient refusal to participate Neuromuscular diseases (eg myopathy, myasthenia gravis) Hematological diseases, bleeding or coagulation disorders Local skin infection and sepsis at the block site Known hypersensitivity to study drugs Morbid obesity (BMI > -35.7 History of alcoholism or drug addiction Any uncompensated systemic disease (cardiovascular, respiratory, metabolic, neurological and endocrine) Other mental or emotional problems that may invalidate informed consent. Patients will be screened by a preoperative care nurse. Potentially eligible individuals will be directed to investigators for screening and additional information. Sleep apnea or any other sleep disorder

Age
From **18 years** old to **65 years** old

Gender
Both

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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of random allocation is the method of random blocks. In this study, the randomization method will be used to generate a random sequence using the block method and the Random allocation software. First, the informed consent form is registered by the patient in writing, and then the participants will be randomly assigned to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description
SNOSE method will be used to hide random allocation. This method is one of the common methods in hiding random allocation. In this method, first a random sequence is created using the mentioned software, then based on the sample size of a number of envelopes with aluminum wrappers (in order to make the content of the envelopes unclear), prepare and each of the random sequences created on It is recorded on a card and the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of starting the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.
اطلاعات بیشتر درباره این نوشتار مبدأ برای اطلاعات ترجمه بیشتر، نوشتار مبدأ لازم است ارسال بازخورد پانلهای کناری

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
2023-02-01, 1401/11/12
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1402.012

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

Severity of patients' pain

Timepoint

zero, 2, 4, 6, 12 and 24 hours after the operation

Method of measurement

Visual Analogue Scale

2

Description

Sedation score

Timepoint

zero hours 2, 4, 6, 12 and 24 after the operation

Method of measurement

Reverse Observer Assessment Scale of
Consciousness/Sedation (OAA/S)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients received 17 ml of 0.25%
bupivacaine + 3 ml of 0.9% saline in a total volume of 20
ml on each side.

Category

Treatment - Drugs

2

Description

Intervention group: Patients received 17 ml of 0.25%
bupivacaine + dexamethasone (4 mg) diluted in 3 ml of
0.9% saline in a total volume of 20 ml on each side.

Category

Treatment - Drugs

3

Description

Intervention group: Patients received 17 ml of 0.25%
bupivacaine + dexmedetomidine (1 µg/kg) diluted in 3
ml of 0.9% saline in a total volume of 20 ml on each side.

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
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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

Moalem Ave

City

Sari

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m.saedi@mazums.ac.ir

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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

Alieh Zamani Kiasari

Position

Associate Professor of Anesthesiology and Vegetative Care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

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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