Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

A Comparison effect of ultrasound bilateral TAP-Block, before start and after the end of surgery, on pain relief in patients underwent laparoscopic cholecystectomy surgery

Protocol summary

Study aim

A Comparison effect of ultrasound bilateral TAP-Block, before start and after the end of surgery, on pain relief in patients underwent laparoscopic cholecystectomy surgery

Design

Clinical trial with parallel groups, double-blind, randomized, phase2 on 60 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Patients referred to Imam Khomeini Hospital in Sari were blinded by a random double-blind method. In this method, a random sequence is first created using the mentioned software, then based on the sample size of the study, a number of envelopes with aluminum wrappers are prepared and each of the random sequences created is recorded on a card, and the card are placed in the envelopes in order. Based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Participants/Inclusion and exclusion criteria

Age 20 to 60 years, physical condition according to ASA, I to II, consent to participate in the study, elective cholecystectomy, no history of opioid use or tolerance to opioid or alcohol, no coagulopathy, no history of sensitivity to bupivacaine, BMI less than equal 35. Absence of neuromuscular disease such as myelopathy and myasthenia gravis, absence of sleep apnea or any other sleep disorder, absence of any uncompensated systemic disease such as cardiovascular, respiratory, metabolic, neurological and endocrinological diseases, absence of History of psychiatric problems, not taking psychiatric drugs, exclusion criteria, conversion of laparoscopic cholecystectomy to open cholecystectomy, uncontrolled bleeding during surgery.

Intervention groups

The group receiving TAP-Block before surgery (Pre-Surgery) The group receiving TAP-Block after surgery (Post-Surgery)

Main outcome variables

Severity of pain-nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211011052726N2**
Registration date: **2023-06-06, 1402/03/16**
Registration timing: **prospective**

Last update: **2023-06-06, 1402/03/16**
Update count: **0**

Registration date

2023-06-06, 1402/03/16

Registrant information

Name

Nafise Faghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

Email address

n.faghani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparison effect of ultrasound bilateral TAP-Block, before start and after the end of surgery, on pain relief in patients underwent laparoscopic cholecystectomy surgery

Public title
A Comparison effect of ultrasound bilateral TAP-Block, before start and after the end of surgery, on pain relief in patients underwent laparoscopic cholecystectomy surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 20 to 60 years Physical status according to ASA, I to II Consent to participate in the study Elective cholecystectomy No history of opioid use or tolerance to opioids or alcohol Absence of coagulopathy No history of bupivacaine allergy BMI less than 35 No neurological disease Musculoskeletal such as myelopathy and myasthenia gravis Absence of sleep apnea or any other sleep disorder Absence of any uncompensated systemic diseases such as cardiovascular diseases Respiratory, metabolic, neurological and endocrinological No history of psychiatric problems Not taking psychiatric drugs
Exclusion criteria:
Conversion of laparoscopic cholecystectomy to open cholecystectomy Uncontrolled bleeding during surgery
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

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

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation by the method of variable 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
In this design, blinding is by random double-blind method. In this way, the person evaluating the patient and the patient himself do not know about the groups to which the patient has been assigned. 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.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Mazandaran University of Medical Sciences, Imam Hospital, Sari
Street address
Amir Mazandarani Blvd. Imam Khomeini Educational and Medical Center
City
Sari
Province
Mazandaran
Postal code
33131 - 48166
Approval date
2023-04-19, 1402/01/30
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1402.009

Health conditions studied

1

Description of health condition studied
general anesthesia
ICD-10 code
T88.59XA

ICD-10 code description
Other complications of anesthesia, initial encounter

Primary outcomes

1

Description
intensity of pain
Timepoint
در ساعت های صفر ، 2، 4، 6، 12 و 24
Method of measurement
The pain intensity of the patients was evaluated based on a visual analogue scale/ it will be evaluated from 0 as no pain to 10 as the most severe pain that the patient has ever experienced.

Secondary outcomes

1

Description
nausea and vomiting
Timepoint
(zero hour), 2, 4, 6, 8, 12 and 24 hours later
Method of measurement
Nausea and vomiting will be recorded using the following scale at 0 to 2 hours and 2 to 24 hours after surgery. The score will be zero in patients who do not have nausea and vomiting. Score 1 in patients with nausea but no vomiting, score 2 in patients who have nausea and vomiting, and score 3 in patients who have more than two bouts of vomiting within 30 minutes.

Intervention groups

1

Description
Intervention group:The recipient of TAP-Block is inserted into the plane with an ultrasound guide of the needle (disposable spinal needle 90 mm, 22 gauge) before the surgery (Pre-Surgery) and after placing the tip of the needle in the fascia between the transversus abdominis and internal oblique muscles, 17 mg bupivacaine 0.25% + 1 µg/Kg dexmedetomidine diluted in 3 ml saline 0.9% in a total volume of 20 ml will receive bilaterally. Bupivacaine, Aburihan, Iran, Dexmedetomidine, Elixir, Iran
Category
Treatment - Drugs

2

Description
Intervention group: The group receiving TAP-Block after surgery (Post-Surgery) and before extubation with an ultrasound guide needle (disposable spinal needle 90 mm, 22 gauge) was inserted into the plane and after placing the tip of the needle in the fascia between the transversus abdominis muscles. and internal oblique, 17 mg bupivacaine 0.25% + 1 µg/Kg dexmedetomidine diluted in 3 ml saline 0.9% in a total volume of 20 ml will receive bilaterally. Bupivacaine, Aburihan, Iran, Dexmedetomidine, Elixir, Iran
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Nafiseh Faghani Makrani
Street address
Amir Mazandarani Blvd.
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3336 1700
Fax
+98 11 3336 1700
Email
dr.nfaghani@gmail.com
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
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
Mazandaran University of Medical Sciences
Full name of responsible person
Nafiseh Faghani Makrani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Amir Mazandarani Blvd.
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3336 1700
Fax
+98 11 3336 1700
Email
dr.nfaghani@gmail.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
Nafiseh Faghani Makrani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Amir Mazandarani Blvd.
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3336 1700
Fax
+98 11 3336 1700
Email
dr.nfaghani@gmail.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
Nafiseh Faghani Makrani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
بلوار امیرمازندرانی
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3336 1700
Fax
+98 11 3336 1700
Email
dr.nfaghani@gmail.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