

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

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 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 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>

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

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