Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigation of the Effect of Intraperitoneal Dexamethasone Combined with Bupivacaine along with Lung Recruitment Maneuver Positioning on Pain, Nausea and Vomiting after Laparoscopic Cholecystectomy

Protocol summary

Study aim

Determining the Effect of Intraperitoneal Dexamethasone Combined with Bupivacaine along with Lung Recruitment Maneuver Positioning on Pain, Nausea and Vomiting after Laparoscopic Cholecystectomy at Imam Khomeini Hospital, Sari, in 2025.

Design

A phase 3, double-blind clinical trial on 80 patients, with a control group and 3 intervention groups, 20 people per group. The random allocation sequence of patients to the study groups was generated using the block randomization method. For this purpose, 8-member blocks and the online software at https://www.sealedenvelope.com were used.

Settings and conduct

After performing the study interventions at Imam Khomeini Hospital in Sari, abdominal and shoulder pain using the VAS tool, and nausea and vomiting using the Emesis Score tool, will be measured by an evaluator at 2, 6, 12, 18, 24, and 48 hours.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 60 years with an ASA physical status of I or II and a body mass index of less than 40 kg/m^2 who are candidates for elective laparoscopic cholecystectomy. Patients with a lack of informed consent, inability to perform the maneuver, or a history of abdominal or shoulder surgery are excluded from the study.

Intervention groups

The first group will only receive the pulmonary maneuver, which includes 5 manual breaths to reach an airway pressure of 40 cmH_2O and maintain it for 5 seconds in the supine position. The second group will be injected intraperitoneally with 40 cc of 0.25% bupivacaine along with 16 mg of dexamethasone, and the patient will be placed in the Trendelenburg position for 10 minutes. The third group will receive both interventions (first the drug, then the maneuver). The control group will undergo standard laparoscopic cholecystectomy without any intervention.

Main outcome variables

Abdominal Pain, Shoulder Pain, Nausea, and Vomiting Following Laparoscopic Cholecystectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251007067533N1**
Registration date: **2025-10-19, 1404/07/27**
Registration timing: **prospective**

Last update: **2025-10-19, 1404/07/27**
Update count: **0**

Registration date

2025-10-19, 1404/07/27

Registrant information

Name

Miad Haddadian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-22, 1404/07/30

Expected recruitment end date

2026-02-19, 1404/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Effect of Intraperitoneal Dexamethasone Combined with Bupivacaine along with Lung Recruitment Maneuver Positioning on Pain, Nausea and Vomiting after Laparoscopic Cholecystectomy

Public title

The Effect of Intraperitoneal Dexamethasone Combined with Bupivacaine plus a Pulmonary Maneuver on Common Complications Following Laparoscopic Cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing elective laparoscopic cholecystectomy who have provided written informed consent Aged 18 to 60 years American Society of Anesthesiologists (ASA) physical status classification of I or II Anticipated surgery duration of less than 2 hours No known history of hypersensitivity to dexamethasone, bupivacaine, or anesthetic agents Body Mass Index (BMI) < 40 kg/m²

Exclusion criteria:

Patients unwilling to participate or who decline to provide informed consent Presence of any contraindication to the pulmonary recruitment maneuver History of previous abdominal or shoulder surgery History of opioid use, alcohol consumption, and long-term use of steroidal and non-steroidal anti-inflammatory drugs History of chronic pain unrelated to gallbladder disease Pregnancy or lactation Presence of significant cardiovascular, pulmonary, renal, hepatic, neurological, or psychiatric diseases; diabetes mellitus; or inflammatory conditions of the shoulder

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient allocation into the four groups will be performed using block randomization with a block size of eight. The randomization list will be generated by the online tool at https://www.sealedenvelope.com. Within this software, the random allocation sequence is automatically produced in the ‘Create a randomization list’ section after specifying the intervention types, block size, and total sample size. To ensure allocation concealment, the randomization list will be managed by an independent third party who is not involved in the core research activities. This procedure will prevent the disclosure of the allocation sequence to the research team members before the patient is definitively assigned to an intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, both the patients and the outcome assessors will be blinded to the group allocation. Patients will be unaware of whether they are in an intervention group or the control group, and the outcome assessors will be unaware of the specific group assignment for each patient. Therefore, this study is a double-blind, randomized controlled trial.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Sari School of Allied Medical Sciences, Mazandaran University of Medical Sciences, Payambar-e-Azam University Complex, 17th Kilometer of Khazarabad Road, Khazar Square

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2025-09-22, 1404/06/31

Ethics committee reference number

IR.MAZUMS.REC.1404.302

Health conditions studied

1

Description of health condition studied

Postoperative Abdominal Pain After Laparoscopic Cholecystectomy

ICD-10 code
ICD-10 code description

2

Description of health condition studied
Postoperative Nausea and Vomiting after Laparoscopic Cholecystectomy
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Postoperative Shoulder Pain After Laparoscopic Cholecystectomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Abdominal Pain
Timepoint
At 2, 6, 12, 18, 24, and 48 hours postoperatively
Method of measurement
Visual Analog Scale

2

Description
Shoulder Pain
Timepoint
At 2, 6, 12, 18, 24, and 48 hours postoperatively
Method of measurement
Visual Analog Scale

3

Description
Postoperative Nausea and Vomiting
Timepoint
At 2, 6, 12, 18, 24, and 48 hours postoperatively
Method of measurement
Emesis Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group one: At the end of the surgery, before the removal of the cannulas and the closure of the incision sites in the abdomen, by changing the reverse Trendelenburg position to the supine position, the Pulmonary Recruitment Maneuver will be administered with 5 high-volume manual breaths until the airway pressure reaches 40 cmH2O. This pressure is maintained for 5 seconds in the supine position. This level of airway pressure is set on the Drager Fabius Plus anesthesia machine and then measured until the desired tidal volume is reached. The cannula valves will be open during the maneuver for CO2 gas to be evacuated.
Category
Treatment - Surgery

2

Description
Intervention group two: At the end of the surgery, before the removal of the cannulas and the closure of the incision sites in the abdomen, 40 cc of 0.25% Bupivacaine combined with 16 mg of Dexamethasone will be injected intraperitoneally. Then, for drug distribution, the patient’s position will be changed from reverse Trendelenburg to the Trendelenburg position. For drug distribution through position change, the patients will remain in the Trendelenburg position for 10 minutes.
Category
Treatment - Surgery

3

Description
Intervention group three: At the end of the surgery, before the removal of the cannulas and the closure of the incision sites in the abdomen, first, 40 cc of 0.25% Bupivacaine combined with 16 mg of Dexamethasone will be injected intraperitoneally. For drug distribution, the patient’s position will be changed from reverse Trendelenburg to the Trendelenburg position, and the patient will be kept in the Trendelenburg position for 10 minutes; then, by changing the position from Trendelenburg to the supine position, the Pulmonary Recruitment Maneuver for CO2 gas evacuation will be performed with 5 high-volume manual breaths until the airway pressure reaches 40 cmH2O. This pressure is maintained for 5 seconds in the supine position. This level of airway pressure is set on the Drager Fabius Plus anesthesia machine and then measured until the desired tidal volume is reached. The cannula valves will be open during the maneuver for CO2 gas to be evacuated.
Category
Treatment - Surgery

4

Description
Control group: Laparoscopic cholecystectomy will be performed according to the surgeon’s standard and routine method, without any additional intervention.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center

Imam Khomeini Educational and Treatment Hospital in Sari

Full name of responsible person
Seyed Mohammad Mehdi Ghaffari Hamedani

Street address
Imam Khomeini Educational and Treatment Center, Razi Street

City
Sari

Province
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4816633131

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Seyed Mohammad Mehdi Ghaffari Hamedani

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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
Miad Haddadian

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Operating Room Technology

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The privacy and confidentiality of all participants' identifying information will be guaranteed throughout every stage of the research, and only anonymized codes will be utilized during data analysis. The dissemination of this study's findings is contingent upon obtaining permission from the Research Ethics Committee of Mazandaran University of Medical Sciences and adhering strictly to all established ethical principles and guidelines.
When the data will become available and for how long
Beginning of the access period from 2026
To whom data/document is available
Researchers affiliated with academic and accredited research institutions
Under which criteria data/document could be used
The de-identified dataset from this study will be made available to qualified researchers upon formal email request to the corresponding author. The research team is committed to maintaining the absolute confidentiality of the original patient data and will only report findings in an aggregated form, in accordance with ethical publication guidelines.
From where data/document is obtainable
Interested researchers can request access to the study data by corresponding with the primary author via email. Email: Diako8358@gmail.com
What processes are involved for a request to access data/document
Upon receiving a formal request via email, the corresponding author will review the conditions for data access. Following approval, the requested dataset will be made available to the applicant within a maximum period of two weeks.
Comments