Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Analgesic Efficacy of the TARAA Block (Transversus Abdominis–Rectus Abdominis Aponeurosis Block) Versus TAP Block and Standard Care in Patients Undergoing Laparoscopic Cholecystectomy: A Three-Arm Randomized Controlled Trial

Protocol summary

Study aim

To compare the analgesic efficacy of Transversus Abdominis Rectus Abdominis Aponeurosis block, Transversus Abdominis Plane block, and standard care in patients undergoing elective laparoscopic cholecystectomy.

Design

Single center, three group, parallel randomized controlled trial with 60 participants, 20 per group. Permuted block randomization with block size 6 and sequentially numbered sealed envelopes will be used. Drug trial phase is not applicable.

Settings and conduct

The trial will be conducted at Imam Hossein Hospital. Blocks will be performed before general anesthesia by an experienced anesthesiologist. Outcome assessment will be performed by a research nurse blinded to group allocation. Data will be coded so that the data analyser remains blinded.

Participants/Inclusion and exclusion criteria

Adults aged 18 to 65 years, with American Society of Anesthesiologists physical status I or II, scheduled for elective laparoscopic cholecystectomy and providing written informed consent will be included. Main exclusion criteria are pregnancy, coagulation disorders, chronic opioid use, local infection at the block site, and allergy to amide local anesthetics.

Intervention groups

The first group receives bilateral ultrasound guided Transversus Abdominis Rectus Abdominis Aponeurosis block. The second receives bilateral ultrasound guided Transversus Abdominis Plane block. Both blocks use 20 mL of 0.2% ropivacaine on each side. The third group receives standard care without a nerve block. All groups receive the same systemic analgesic protocol and rescue morphine when required.

Main outcome variables

Total intravenous morphine consumption during the first 24 hours; pain scores at rest and movement at 2, 4, 6, 12, and 24 hours; time to first rescue analgesia; postoperative nausea and vomiting; patient satisfaction; block related adverse events.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260704070072N1**
Registration date: **2026-08-15, 1405/05/24**
Registration timing: **prospective**

Last update: **2026-08-15, 1405/05/24**
Update count: **0**

Registration date

2026-08-15, 1405/05/24

Registrant information

Name
Moein Ebrahimi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-09-20, 1405/06/29

Expected recruitment end date

2026-12-20, 1405/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic Efficacy of the TARAA Block (Transversus Abdominis–Rectus Abdominis Aponeurosis Block) Versus TAP Block and Standard Care in Patients Undergoing Laparoscopic Cholecystectomy: A Three-Arm Randomized Controlled Trial

Public title

Comparison of Two Abdominal Nerve Blocks and Standard Pain Treatment for Pain Relief After Laparoscopic Gallbladder Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients scheduled for elective laparoscopic cholecystectomy Age between 18 and 65 years American Society of Anesthesiologists (ASA) physical status I or II Proviبهدل of written informed consent to participate in the study.

Exclusion criteria:

History of allergy to amide local anesthetics. Coagulation disorder defined as platelet count below 80,000/µL or INR above 1.5. Chronic opioid use for more than 3 months. Local infection at the planned block injection site. Pregnancy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomized individually in a 1:1:1 ratio to the TARAA block, TAP block, or standard care group. Balanced permuted block randomization with a block size of 6 will be used. The random allocation sequence will be generated by an independent person who is not involved in participant enrollment or implementation of the interventions. No stratification will be used. Group assignments will be placed in sequentially numbered, sealed envelopes. The envelopes will be opened only after participant enrollment and confirmation of eligibility criteria. Therefore, allocation concealment will be maintained until group assignment.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The anesthesiologist performing the regional block cannot be blinded to group allocation because the TARAA and TAP techniques are different and the standard-care group does not receive a nerve block. Therefore, the investigator responsible for performing the intervention is not blinded. Participants are not considered blinded because no sham block is performed in the standard-care group. The outcome assessor and data collector will be blinded to group allocation. Postoperative outcomes, including pain scores, morphine consumption, postoperative nausea and vomiting, patient satisfaction, and block-related adverse events, will be recorded by a research nurse who is unaware of the allocated study group. The statistical data analyser will also remain blinded to group allocation. Study groups will be coded before statistical analysis so that the analyser cannot identify the intervention corresponding to each code. No Data and Safety Monitoring Board is planned for this trial.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine - Shahid Beheshti University of Medical Sciences (Research Ethics Committee)

Street address

Shahid Chamran Highway- Evin- next to Taleghani Hospital- Medical School- third floor

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2026-08-11, 1405/05/20

Ethics committee reference number

IR.SBMU.MSP.REC.1405.365

Health conditions studied

1

Description of health condition studied

Acute postoperative pain after laparoscopic cholecystectomy

ICD-10 code

K80.2

ICD-10 code description

Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description

Total intravenous morphine consumption during the first 24 hours after surgery, measured in milligrams.

Timepoint

From the end of surgery until 24 hours after surgery.

Method of measurement

The cumulative dose of intravenous morphine administered as rescue analgesia during the first 24 hours after surgery will be recorded in milligrams using the medication administration record.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before induction of general anesthesia, bilateral ultrasound guided Transversus Abdominis Rectus Abdominis Aponeurosis block will be performed by an anesthesiologist experienced in regional anesthesia. A linear ultrasound probe will be placed in the supraumbilical region, lateral to the midline. After identification of the rectus abdominis and transversus abdominis aponeurotic layers, the block needle will be advanced using an in plane technique. Twenty milliliters of 0.2% ropivacaine will be injected on each side in the targeted aponeurotic plane. Patients will also receive the standard systemic postoperative analgesic protocol used in all study groups.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hosein Hospital

Full name of responsible person

Alireza Shakeri

Street address

Emam Hosein Hospital - Shahid Madani St - Tehran - Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Shakeri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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
Deidentified individual participant data and data dictionary. The dataset will include deidentified participant-level demographic, clinical, intervention, and outcome data collected during the trial, including morphine consumption, postoperative pain scores, time to first rescue analgesia, postoperative nausea and vomiting, patient satisfaction, and block-related adverse events. Direct personal identifiers will not be shared.
When the data will become available and for how long
After data collection completion
To whom data/document is available
Other researchers
Under which criteria data/document could be used
belonging to academic institution
From where data/document is obtainable
researcher's personal email: dr.alirezashakeri@gmail.com
What processes are involved for a request to access data/document
requesting by email
Comments