Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of transversus abdominis nerve block with rectus sheath nerve block in pain control after laparoscopic cholecystectomy

Protocol summary

Study aim
To compare transversus abdominis plane block (TAP block) with rectus sheath block (RSB) for pain control after elective laparoscopic cholecystectomy.

Design
Single center, parallel group, randomized controlled trial; total sample size 60; allocation ratio 1 to 1; phase not applicable; individual simple randomization using sequentially numbered opaque sealed envelopes. Participants, postoperative clinical staff, data collectors, outcome assessors and statisticians are blinded; the block performer is not blinded.

Settings and conduct
Imam Khomeini Hospital Complex; blocks performed under ultrasound guidance; identical dressings applied; outcomes recorded at prespecified time points.

Participants/Inclusion and exclusion criteria
Adults aged 20 to 60 years; American Society of Anesthesiologists physical status I or II (ASA); body mass index 18 to 35; elective laparoscopic cholecystectomy; written informed consent. Main exclusion criteria: refusal; allergy to local anesthetics; coagulopathy; local infection at the injection site; alcohol or substance misuse; major psychiatric disorder; significant chronic painful disease; failed block; operative time more than 3 hours; intraoperative complications.

Intervention groups
Group A receives ultrasound guided TAP block with 20 mL bupivacaine 0.25 percent after induction of general anesthesia and before incision. Group B receives ultrasound guided RSB with 20 mL bupivacaine 0.25 percent at the same time point. Perioperative anesthesia and postoperative analgesia are standardized in both groups.

Main outcome variables
ain intensity by visual analogue scale (VAS) at 2, 6, 12 and 24 hours after surgery; cumulative opioid consumption within 24 hours; need for intraoperative fentanyl and recovery ketorolac; block related complications.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230130057273N3**
Registration date: **2025-12-17, 1404/09/26**
Registration timing: **prospective**

Last update: **2025-12-17, 1404/09/26**
Update count: **0**

Registration date
2025-12-17, 1404/09/26

Registrant information

Name
babak eslami

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2026-06-21, 1405/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

Comparative study of transversus abdominis nerve block with rectus sheath nerve block in pain control after laparoscopic cholecystectomy

Public title

Comparative study of transversus abdominis nerve block with rectus sheath nerve block in pain control after laparoscopic cholecystectomy in patients of Imam Khomeini Hospital Complex, 2026

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

ASA class I & II Informed consent to participate in the project BMI between 18 and 35

Exclusion criteria:

Allergy to anesthetic drugs used in the plan failure of the chosen method Patient's unwillingness to participate in the plan Localized sepsis at the site of the block Alcohol or drug abuse History of any coagulation disorder Surgery time more than 3 hours Surgeries in which the patient experiences surgical complications during the operation for any reason Any mental or psychological disorder History of serious painful illness

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this randomized clinical trial, eligible patients will be allocated after confirmation of the inclusion/exclusion criteria and obtaining written informed consent. Participants will be assigned using simple randomization with a 1:1 allocation ratio to one of the following two groups: the TAP block group (transversus abdominis plane block) and the rectus sheath block group. 1) Randomization method Type of randomization: Simple randomization (without blocking and without stratification). For each participant, an independent random assignment will be generated and allocated to one of two groups (A/B). Quasi-random methods (e.g., alternating assignment, date of birth, medical record number, day of visit, etc.) will not be used. 2) Unit of randomization Unit: Individual randomization; each patient constitutes an independent unit for allocation. Cluster or multilevel randomization will not be performed in this study. 3) Stratification Stratified randomization will not be used. All eligible participants will enter the randomization process without stratification. 4) Randomization tools Random sequence generation tool: Computer-generated random numbers using SPSS. Allocation implementation at the bedside: Sequentially numbered, opaque, sealed envelopes (SNOSE). 5) Generation of the random sequence The allocation sequence will be generated by an individual independent of the clinical implementation team. A list of assignments with a length equal to the required sample size will be created, and for each entry, allocation to A or B will be generated with equal probability (0.5/0.5). The final output will be a serial list in which each sequential number corresponds to a specific allocation (A/B). 6) Allocation concealment To minimize selection bias, allocation concealment will be ensured using the SNOSE method. Envelopes will be opaque, light-impermeable, sealed, and sequentially numbered. Each envelope will contain a card indicating the group code (A = TAP, B = Rectus Sheath). Envelopes will be prepared by an independent person and stored securely. The envelope will be opened only after final confirmation of patient eligibility and documentation of written informed consent.

Blinding (investigator's opinion)

Double blinded

Blinding description

To minimize bias, participants, postoperative care staff, data collectors, and outcome assessors will be blinded to group allocation. The blocks will be performed after induction of general anesthesia, and identical dressings will be applied over the injection sites. Group allocation will be implemented using sequentially numbered, opaque, sealed envelopes (SNOSE) and will be disclosed only to the anesthesiologist performing the block; in documents accessible to outcome assessors, allocation will be recorded only as code A/B. The postoperative pain management protocol will be identical and pre-standardized in both groups. Statistical analyses will be conducted using coded groups, and unblinding will take place only after database lock.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd., Central Building of Tehran University of Medical Sciences

City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2025-09-30, 1404/07/08
Ethics committee reference number
IR.TUMS.IKHC.REC.1404.301

Health conditions studied

1

Description of health condition studied
Acute pain occurring in the early postoperative period after elective laparoscopic cholecystectomy, requiring postoperative analgesia.
ICD-10 code
R52
ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Postoperative pain intensity at rest
Timepoint
2, 6, 12, and 24 hours after surgery
Method of measurement
Visual analogue scale, a 10 centimetre line anchored by no pain and worst imaginable pain

2

Description
Cumulative intravenous morphine dose administered during the first 24 hours after surgery
Timepoint
From the end of surgery to 24 hours after surgery
Method of measurement
Total intravenous morphine dose extracted from the medication administration record and patient chart

Secondary outcomes

1

Description
Total intravenous fentanyl dose administered intraoperatively
Timepoint
At the end of surgery, as the cumulative dose from induction of anesthesia to the end of surgery
Method of measurement
Total intravenous fentanyl dose extracted from the anesthesia record and intraoperative medication chart

2

Description
Need for intravenous ketorolac administration in the post anesthesia care unit
Timepoint
During the post anesthesia care unit stay, from admission to discharge
Method of measurement
Documentation of intravenous ketorolac administration in the post anesthesia care unit medication administration record

3

Description
Incidence of block related complications
Timepoint
During block performance and up to 24 hours after surgery
Method of measurement
Clinical assessment and documentation of adverse events including injection site hematoma or bleeding, signs of local infection, signs of local anesthetic systemic toxicity, and any other reported adverse events

Intervention groups

1

Description
Intervention group: After induction of general anesthesia and before surgical incision, participants receive an ultrasound guided transversus abdominis plane block. A total of 20 millilitres of bupivacaine 0.25 percent is injected into the appropriate plane. All other anesthesia components and the postoperative pain management protocol are standardized according to the study protocol.
Category
Treatment - Drugs

2

Description
Intervention group: After induction of general anesthesia and before surgical incision, participants receive an ultrasound guided rectus sheath block. A total of 20 millilitres of bupivacaine 0.25 percent is injected into the rectus sheath plane. All other anesthesia components and the postoperative pain management protocol are standardized according to the study protocol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person

Babak Eslami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Babak Eslami

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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