# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 8889 5913
**Email address**
beslami@sina.tums.ac.ir


**Recruitment status**
**Recruitment complete**
**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

**Street address**
Baqerkhan Ave, Chamran Highway, Imam Khomeini Hospital

**City**
Tehran

**Province**
Tehran

**Postal code**
1419733141

**Phone**
+98 21 6119 0000

**Email**
Babak.eslaami@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Dr. Ramin Kordi

**Street address**
Keshavarz Blvd., corner of Qods St., Central Organization of the University, 6th floor of Research and Technology Vice-Cancellor

**City**
Tehran

**Province**
Tehran

**Postal code**
1417653761

**Phone**
+98 21 8163 3685

**Email**
rmo@tums.ac.ir

**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

**Street address**
Baqerkhan Ave, Chamran Highway

**City**
Tehran

**Province**
Tehran

**Postal code**
1419733141

**Phone**
+98 21 6119 0000

**Email**
beslami@sina.tums.ac.ir

## Person responsible for scientific 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

**Street address**
Baqerkhan Ave, Chamran Highway

**City**
Tehran

**Province**
Tehran

**Postal code**
1419733141

**Phone**
+98 21 6119 0000

**Email**
beslami@sina.tums.ac.ir

## Person responsible for updating data

**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

**Street address**

Baqerkhan Ave, Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 0000

**Email**

beslami@sina.tums.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