Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the palliative efficacy of adding calcitonin to ropivacaine in subcostal transverse abdominal plane (STAP) block for laparoscopic cholecystectomy

Protocol summary

Study aim

Comparison of time to first rescue analgesic inpatients receiving STAP block with ropivacaine and calcitonin and patients receiving ropivacaine alone.

Design

A clinical trial with 2 groups, with parallel groups, triple-blinded, randomized, phase 3 on 36 patients. For randomization, simple randomization is used using a random number table.

Settings and conduct

The STAP block is performed under ultrasound guidance and using a linear probe. After determining the layer of abdominal wall muscles (external oblique, internal oblique, and transverse abdominis), the needle is inserted into the space between the internal oblique muscle and the transverse abdominis muscle and the drug solution is injected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mental health, adequate understanding and awareness of the patient and providing informed consent for all laparoscopic cholecystectomy surgeries

Intervention groups

RC Group (Ropivacaine with Calcitonin): - Bilateral Subcoastal TAP Block with 20 mL Ropivacaine 0.2% Solution + 50 Calcitonin Units on Each Side Group R (Ropivacaine only): - Bilateral subcostal TAP block with 0.2% ropivacaine with a volume of 20 mL for each side (containing normal saline as a placebo instead of calcitonin) Postoperative data: Time to first rescue palliative, VAS pain scores will be measured at 0, 2, 4, 6, 12, and 24 hours, total opioid intake, and incidence of adverse events (e.g., nausea, vomiting, itching)

Main outcome variables

Time to the first rescue analgesic

General information

Reason for update

Recruitment has been completed, so the actual recruitment dates were updated. The VAS assessment time points were updated in accordance with the ethics-approved protocol, and the 4-hour time point was removed. It had been entered mistakenly in the initial registration.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240826062868N1**
Registration date: **2025-04-08, 1404/01/19**
Registration timing: **prospective**

Last update: **2026-09-07, 1405/06/16**
Update count: **1**

Registration date

2025-04-08, 1404/01/19

Registrant information

Name

Seyed Mohammad Seyed Alshohadaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 23515

Email address

sinsinasin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-07, 1403/12/17

Expected recruitment end date

2025-06-07, 1404/03/17

Actual recruitment start date
2025-04-20, 1404/01/31
Actual recruitment end date
2026-05-21, 1405/02/31
Trial completion date
empty

Scientific title
Evaluation of the palliative efficacy of adding calcitonin to ropivacaine in subcostal transverse abdominal plane (STAP) block for laparoscopic cholecystectomy

Public title
Evaluation of analgesia for patients undergoing laparoscopic cholecystectomy using ropivacaine and calcitonin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 - 65 Elective laparoscopic cholecystectomy surgery ASA (American Society of Anesthesiologists) I-II patients
Exclusion criteria:
Contraindications for regional block Study drugs allergy Pregnancy Chronic pain drug users Cognitive disorders Substance and palliative drug addiction
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Actual sample size reached: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, a simple randomization method was used using a table of random numbers and through the Random generator program. In this randomization, patients who meet the criteria for entering the study are assigned a number before anesthesia, which will represent one of the two study groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Syringes containing study drugs are prepared identically by a person who is not involved in the care of the patients. Anesthesiologists, patients, outcome evaluators and data analyzer will be unaware of group allocation to ensure unbiased results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Yaman st., Shahid Chamran Hwy.
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2025-01-11, 1403/10/22
Ethics committee reference number
IR.SBMU.RETECH.REC.1403.687

Health conditions studied

1

Description of health condition studied
Analgesia after laparoscopic cholecystectomy surgery
ICD-10 code
K81.0
ICD-10 code description
Acute cholecystitis

Primary outcomes

1

Description
First time to need rescue analgesic
Timepoint
24 hours after surgery
Method of measurement
Hour

Secondary outcomes

1

Description
Pain in rest
Timepoint
0, 2 ,6 ,12, 24 hours Postoperative
Method of measurement
Visual analog scale

2

Description
Perioperative opioid consumption
Timepoint
Perioperative and to 24 after surgery
Method of measurement
Patient file information

3

Description
Side effects incidence
Timepoint
Yes or no
Method of measurement
Patient file record

Intervention groups

1

Description
Intervention group: RC group (ropivacaine with calcitonin): - Bilateral STAP (Subcostal Transversus Abdominis Plane Block) with 20 mL ropivacaine solution 0.2% + 50 calcitonin units on each side
Category
Treatment - Drugs

2

Description
Control group: Group R (ropivacaine only): - Bilateral STAP block with 0.2% ropivacaine with a volume of 20 mL for each side (containing normal saline as a placebo instead of calcitonin)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Alireza Shakeri
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2

Recruitment center
Name of recruitment center
Shahid Modarres Hospital
Full name of responsible person
Maede Karimian
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Saadat abad Blv, Saadat abad crossing with Yadegar Emam Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Vice President for Research, Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway, Tehrani, Iran.
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Grant name
Grant to Young Assistant Professors of Ministry, Pioneer Grant
Grant code / Reference number
4040/700/د
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
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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1998734383
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Email
Sinsinasin@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
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