

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Street address

Shahid Madani st

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1617763141

Phone

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Email

dr.alirezashakeri@gmail.com

Web page address

<https://modarres.sbm.ac.ir/>

2

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Maede Karimian

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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

4040/700/3

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

+98 21 7343 0000

Email

dr.alirezashakeri@gmail.com

Person responsible for updating data**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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Seyed Mohammad Seyed alshohadaei

Position

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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City

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Postal code

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Phone**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