

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Erector Spine Block and External Oblique Intercostal Block with Ultrasonography Guided to pain control after laparoscopic cholecystectomy surgery a clinical trial

Protocol summary

Study aim

Comparison of Erector Spine Block and External Oblique Intercostal Block with Ultrasonography Guided to pain control after laparoscopic cholecystectomy surgery a clinical trial

Design

Clinical trial, parallel groups, double-blind, randomized, on 28 patients. In order to randomize, the block randomization method will be used.

Settings and conduct

Patient candidates for laparoscopic cholecystectomy surgery referring to Firouzgar Hospital in Tehran will be included in the study. Patients will be randomly divided into 2 groups based on blocks of 4. Patients, responsible for data collection, analysis and outcome assessment will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient candidates for laparoscopic cholecystectomy surgery, The age range from 20 to 60 years. Exclusion criteria: Coagulation disorders, Neurological disorders.

Intervention groups

Intervention group 1: In the erector spinae block group, the patient will be placed in the lateral position, then by examining the injection site and monitoring and necessary preparation, with the help of ultrasound guidance, the correct injection site on the transverse process of the 6th vertebra will be determined and inserted under ultrasound guidance. After reaching the site, after effective aspiration, 20 ml of 0.2% ropivacaine will be injected. Intervention Group 2: In the external oblique intercostal block group, the patient will be placed in the supine position, then, by examining the injection site, monitoring, and necessary preparation, with the help of ultrasound guidance, the correct injection site will be determined in the mid-axillary line near the 6-7th rib, and the patient will be inserted under ultrasound

guidance. After reaching the site, after effective aspiration, 20 ml of 0.2% ropivacaine will be injected.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230518058225N9**

Registration date: **2025-02-22, 1403/12/04**

Registration timing: **prospective**

Last update: **2025-02-22, 1403/12/04**

Update count: **0**

Registration date

2025-02-22, 1403/12/04

Registrant information

Name

Anahita Sadri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8670 2543

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-10, 1403/12/20

Expected recruitment end date

2025-09-11, 1404/06/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Erector Spine Block and External Oblique Intercostal Block with Ultrasonography Guided to pain control after laparoscopic cholecystectomy surgery a clinical trial

Public title
Effect of Erector Spine Block and External Oblique Intercostal Block with Ultrasonography Guided to pain control

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient candidates for laparoscopic cholecystectomy surgery The age range from 20 to 60 years
Exclusion criteria:
Severe pulmonary disease Neurological disorders

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: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into 2 groups. The randomization tool will randomize the table of numbers. Block randomization method will be used for randomization. Block randomization is for the purpose of making sure that exactly equal number of participants enter the study groups. The advantages of block randomization are that the balance of the number of participants in each group is guaranteed. For this purpose, 4 blocks will be formed and in each block 2 people from intervention group and 2 people will be placed in the control group. A total of 7 blocks will be considered to reach the sample size. Blocks contain numbers, numbers represent study groups. Their order will be determined by the statistician from the beginning. In order to hide the random allocation, opaque envelopes sealed with a random sequence will be used. In this method, each of the generated random sequences will be recorded on a card and the cards will be placed in the envelopes in order. became. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter

envelopes is glued and placed in a box. At the time of registration of participants, based on the order of entry of qualified participants into the study, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will be aware that they will be randomly assigned to one of the two study groups, but will not know which method will be provided in that group. Patients will be assigned to one of two groups using a random number table. The person in charge of data collection, the analyst and the outcome evaluator will collect and analyze the information based on groups 1 and 2 and will not know the type of treatment in the groups and will be kept blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Medicine - Iran University of Medical Sciences (Research Ethics Committee)
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535

Approval date
2024-09-29, 1403/07/08

Ethics committee reference number
IR.IUMS.FMD.REC.1403.305

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
G89
ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

at 0, 2, 6, 12, 24 hours after surgery

Method of measurement

Numerical pain rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the erector spinae block group, the patient will be placed in the lateral position, then by examining the injection site and monitoring and necessary preparation, with the help of ultrasound guidance, the correct injection site on the transverse process of the 6th vertebra will be determined and inserted under ultrasound guidance. After reaching the site, after effective aspiration, 20 ml of 0.2% ropivacaine (manufacturer: Varian Pharmed) will be injected.

Category

Treatment - Other

2

Description

Intervention Group 2: In the external oblique intercostal block group, the patient will be placed in the supine position, then, by examining the injection site, monitoring, and necessary preparation, with the help of ultrasound guidance, the correct injection site will be determined in the mid-axillary line near the 6-7th rib, and the patient will be inserted under ultrasound guidance. After reaching the site, after effective aspiration, 20 ml of 0.2% ropivacaine (manufacturer: Varian Pharmed) will be injected.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar hospital

Full name of responsible person

Nafiseh Tavakoli

Street address

Beh Afarin Ave, Vali Asr Sq.

City

Tehran

Province

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Nafiseh Tavakoli

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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