Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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% rupivacaine 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% rupivacaine 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)

Phone

+98 21 8670 2543

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sadri.anahita@gmail.com

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% rupivacaine (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% rupivacaine (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
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Sponsors / Funding sources

1

Sponsor
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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
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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