# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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

**Email address**

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
**Street address**
Beh Afarin Ave, Vali Asr Sq.
**City**
Tehran
**Province**
Tehran
**Postal code**
1593747811
**Phone**
+98 21 8214 1600
**Email**
h_firoozgar@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Majid Safa
**Street address**
Iran University of Medical Sciences, Hemmat Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 21 8670 2503
**Email**
research@iums.ac.ir
**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
**Street address**
Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave
**City**
Tehran

**Province**
Tehran
**Postal code**
1445613131
**Phone**
+98 21 6435 2222
**Email**
ntvk1356@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Soudabeh Jalali Motlagh
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
Beh Afarin Ave, Vali Asr Sq
**City**
Tehran
**Province**
Tehran
**Postal code**
1593747811
**Phone**
+98 21 8214 1600
**Email**
djalalimotlagh.s@iums.ac.ir

## Person responsible for updating data

**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
**Street address**
Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave
**City**
Tehran
**Province**
Tehran
**Postal code**
1445613131
**Phone**
+98 21 6435 2222
**Email**
ntvk1356@gmail.com

## 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