

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparison effect of ultrasound guided erector spinalis plane block and parascapular sub ilio-costalis plane block on the pain control after video associated thoracic surgery

Protocol summary

Study aim

Comparison effect of ultrasound guided erector spinalis plane block and parascapular sub ilio-costalis plane block on the postoperative pain control after video associated thoracic surgery

Design

Clinical trial, parallel groups, double-blind, randomized, phase 3 on 40 patients. In order to randomize, the block randomization method will be used.

Settings and conduct

In this research, all patients requiring video associated thoracic surgery, referred to Firouzgar and Rasoul Akram Hospitals in Tehran, will be included in the study. Patients will be randomly divided into 2 groups based on blocks of 4. The sample size for each study group is 30 people. A total of 40 patients will be examined. Patients, surgeon and data analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing video associated thoracic surgery, A person with normal health, A person with mild systemic disease, Age between 20-60 years. Non-entry criteria: Emergency patients with organic problems, History of sensitivity to ropivacaine, Patients who have received analgesics in the last day, Patients with body mass index less than 35, Patients with underlying liver and kidney disease and coagulopathy or a history thereof, Patients who are addicted to opioids.

Intervention groups

Intervention group 1: In this group, before the start of surgery, patients under erector spina plain block are placed under ultrasound guidance with a linear prop on the surgical side. Intervention group 2: In the second group, before the start of surgery, patients are placed under sub ilio-costalis block with the help of ultrasound guidance with a linear prop on the surgical side

Main outcome variables

Severity of patients' pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230518058225N1**

Registration date: **2023-06-23, 1402/04/02**

Registration timing: **prospective**

Last update: **2023-06-23, 1402/04/02**

Update count: **0**

Registration date

2023-06-23, 1402/04/02

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

2023-07-06, 1402/04/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of ultrasound guided erector spinalis plane block and parascapular sub ilio-costalis plane block on the pain control after video associated thoracic surgery

Public title

Effect of ultrasound guided erector spinalis plane block and parascapular sub ilio-costalis plane block on the pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing video associated thoracic surgery A person with normal health A person with mild systemic disease Age between 20-60 years

Exclusion criteria:

Emergency patients with organic problems History of sensitivity to ropivacaine Patients who have received analgesics in the last day Patients with body mass index less than 35 Patients with underlying liver and kidney disease and coagulopathy or a history thereof Patients who are addicted to opioids.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups. The randomization tool will be a random sequence generation software called SAS. In addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method. 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 in control group will be placed. A total of 10 blocks will be considered to reach the sample size. The blocks contain numbers, odd numbers represent the intervention group and even numbers represent the control group. Their order will be determined by the software initially. 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 respectively will be

placed in the envelopes. 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 blinded to the type of block. Patients will be aware that they will be randomly assigned to one of the two treatment groups, but will not know which block 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 data based on groups 1 and 2 and will not know the type of treatment provided 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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-02-08, 1401/11/19

Ethics committee reference number

IR.IUMS.FMD.REC.1401.643

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

Severity of patients' pain

Timepoint

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

Method of measurement

Numerical pain rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, before the start of surgery, patients under erector spina plain block are placed under ultrasound guidance with a linear prop on the surgical side. After monitoring, the patients are placed in a sitting position, and on the surgical side, after the probe and drape, the linear ultrasound probe is placed longitudinally in alignment with the T4 vertebra (transverse process) and after defining the transverse processes edge of the upper and lower vertebral, the needle enters the skin and subcutaneous tissue and is directed to the erector spinae plane muscle. A volume of 20 cc of ropivacaine 0.5% (Manufacturing company: Varian Pharmed) is injected into the fascia of the erector spinae plain muscle (behind the transverse process).

Category

Treatment - Other

2

Description

Intervention group 2: In the second group, before the start of surgery, patients are placed under sub ilio-costalis block with the help of ultrasound guidance with a linear prop on the surgical side. After monitoring, the patients are placed in a sitting position and the hands are placed by the patient's side, and on the surgical side, after probe and drape, a linear ultrasound probe is placed longitudinally and aligned with the T4 vertebra in the parasagittal axis, and after defining the inner edge of the scapula and the edge of its spinous process, we insert the needle 2 cm medial to the spinous process of the scapula and proceed towards the caudal or cranial side to reach the ili-ocostal-intercostal fascia in the vicinity of the fourth rib and after ensuring the location of the needle with 2 cc Saline, a volume of 20 cc of ropivacaine 0.5% (Manufacturing company: Varian Pharmed) is injected in that place.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-Akram Hospital

Full name of responsible person

Soheil Fath Allah Zadeh Noor

Street address

Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2222

Email

Rasoolhospital@iums.ac.ir

2

Recruitment center

Name of recruitment center

Firouzgar hospital

Full name of responsible person

Soheil Fath Allah Zadeh Noor

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

Hossein Keyvani

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

Poupak Rahimzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 6650 9059

Email

p-rahimzadeh@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City

تهران

Province

Tehran

Postal code

1433933111

Phone

+98 21 6650 9059

Email

p-rahimzadeh@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Soheil Fath Allah Zadeh Noor

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 2533

Email

soheilfzn@yahoo.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