Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison serratus anterior block versus intraoperative continuous infusion of ketodex in acute pain management of thoracotomy-Randomized clinical trial

Protocol summary

Study aim

Comparison serratus anterior block versus intraoperative continuous infusion of ketodex in acute pain management of thoracotomy-Randomized clinical trial

Design

This is a double-blind, block-randomized clinical trial, phase 2-3, with 50 patients in two parallel groups. Randomization sequence was generated via www.sealedenvelope.com.

Settings and conduct

This study is conducted at Abu Ali Sina Hospital. Patients are randomly assigned to intervention and control groups after anesthesia induction. The anesthesiologist performing the interventions is aware of the group assignments, whereas the clinical assessor and statistical analyst are blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria The major inclusion criteria are adult patients aged 18 years and older who are scheduled for elective thoracotomy and have the ability to provide informed and voluntary consent to participate in the study. Exclusion Criteria The major exclusion criteria include allergy to study medications, coagulation disorders or use of anticoagulants, psychiatric or cognitive disorders affecting the ability to provide informed consent, chronic use of opioids or other analgesics, and a history of previous chest surgery.

Intervention groups

Intervention group (SAB): Patients immediately after anesthesia induction receive 20 ml of 0.25% bupivacaine injected at the mid-axillary line at the level of the fifth rib, between the serratus anterior muscle and the intercostal muscles on the operative side. Control group (ICK): Patients receive a continuous intravenous infusion of ketamine at a dose of 5 to 7.5 micrograms per kilogram per minute and Dexmedetomidine at a dose of 0.3 to 1 microgram per kilogram per hour through a single intravenous line under the supervision of an anesthesiologist after anesthesia induction.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250609066132N1**
Registration date: **2025-07-07, 1404/04/16**
Registration timing: **prospective**

Last update: **2025-07-07, 1404/04/16**
Update count: **0**

Registration date

2025-07-07, 1404/04/16

Registrant information

Name

Fateme Khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 1460

Email address

khalili_fa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-21, 1404/04/30

Expected recruitment end date

2026-05-20, 1405/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison serratus anterior block versus intraoperative continuous infusion of ketodex in acute pain management of thoracotomy-Randomized clinical trial

Public title

Comparison of Two Pain Control Methods After Chest Surgery: Anterior Rib Muscle Block Injection versus Continuous Infusion of the Anesthetic Drug Ketodex

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients aged 18 years and older Candidates scheduled for elective thoracotomy Ability to provide informed and voluntary consent to participate in the study

Exclusion criteria:

Allergy to study medications Coagulation disorders or use of anticoagulants Psychiatric or cognitive disorders affecting informed consent Chronic use of opioids or analgesics History of previous chest surgery

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to two groups using block randomization. In this method, blocks of sizes 4 and 6 are created, each containing an equal number of patients from groups A and B arranged in alternating permutations. Then, 10 blocks are randomly selected, and patients are allocated equally and randomly to the two groups according to the sequences within these blocks. The block randomization sequence will be generated using the website www.sealedenvelope.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a double-blind trial. Patients are under general anesthesia during the interventions and are unaware of their group allocation. The only individual aware of the group assignments is the anesthesiologist performing the interventions, who does not participate in clinical assessments or data analysis. Additionally, the clinical assessor responsible for data collection and outcome evaluation, as well as the statistical analyst who processes and analyzes the data, are fully blinded to the patients' group allocations.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz Medical School

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

197871345

Approval date

2025-05-07, 1404/02/17

Ethics committee reference number

IR.SUMS.MED.REC.1404.118

Health conditions studied

1

Description of health condition studied

Thoracotomy

ICD-10 code

S27.0

ICD-10 code description

Traumatic pneumothorax

Primary outcomes

1

Description

Nausea and Vomiting

Timepoint

Immediately after surgery, 2, 4, 8, 12, and 24 hours post-op

Method of measurement

PONV score (presence/absence)

2

Description

Arterial Oxygen Saturation (O2 Sat)

Timepoint
Upon arrival to OR, then every 15 minutes until end of surgery and in recovery
Method of measurement
Based on the patient's medical record

3

Description
Pain
Timepoint
Immediately after surgery, 1, 6, 12, and 24 hours post-op
Method of measurement
VAS scale (pain score)

4

Description
Patient Satisfaction with Pain Management
Timepoint
Postoperative period
Method of measurement
Likert scale

5

Description
Prescribed Morphine Dose
Timepoint
First 24 hours post-op
Method of measurement
Total morphine dose (mg)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group (Serratus Anterior Block - SAB):Participants in the SAB group will receive an ultrasound-guided serratus anterior block immediately after anesthesia induction. Using a 22-gauge, 50 mm needle and in the lateral decubitus position, 20 ml of 0.25% Bupivacaine will be injected at the mid-axillary line at the level of the fifth rib, between the serratus anterior muscle and the intercostal muscles on the operative side. This procedure will be performed under sterile conditions with close monitoring for any signs of systemic local anesthetic toxicity prior to the surgical incision. It is noteworthy that the anesthesia induction, maintenance, and all perioperative care will be conducted identically and according to a standardized protocol in both groups.
Category
Treatment - Drugs

2

Description
Control Group (Continuous Infusion of Ketodex - ICK):Participants in the ICK group will receive a continuous intravenous infusion of ketamine and Dexmedetomidine immediately after anesthesia induction. Ketamine will be infused at a rate of 5 to 7.5 mcg/kg/min, and Dexmedetomidine at 0.3 to 1 mcg/kg/hour through a single intravenous line under the supervision of an anesthesiology specialist. It is important to note that anesthesia induction, maintenance, and all perioperative care will be conducted identically and according to a standardized protocol in both groups.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Abu-Alisina hospital
Full name of responsible person
Shadi Oboodi
Street address
No. 958, Boostan Blvd, Sadra New City.
City
Shiraz
Province
Fars
Postal code
7199467985
Phone
+98 71 3344 0000
Email
abualisinacharity@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street.
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3628 1460
Email
monakhalilimd@gmail.com
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Shadi Oboodi
Position
MD/resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Anesthesia Department- Operation Room- Nemazee Hospital- Zande Blvd.
City
Shiraz
Province
Fars
Postal code
7193711351
Phone
+98 71 3628 1460
Email
sh_oboudi@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fateme Khalili
Position
Fellowship of Intra-abdominal organ transplantationAnesthesia
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesia Department- Operation Room- Nemazee Hospital- Zande Blvd.
City
Shiraz
Province
Fars
Postal code
7193711351
Phone
+98 71 3628 1460
Email
khalili_fa@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamide Saeedizade
Position
Research Assisstant
Latest degree
Master
Other areas of specialty/work
Medical Informatics
Street address
Anesthesiology Department, Faghihi Hospital, Zand Street.
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
009836281460
Email
saeedi.hamide@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