Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effect of epidural catheter with ketamine drip in analgesia after elective thoracotomies

Protocol summary

Study aim
In this study, the level of analgesia of epidural catheter and ketamine drip after thoracotomy was compared, and the effect of these two methods of analgesia on blood pressure, heart rate, and respiratory rate was also examined.

Design
A phase 2 randomized, single-blind, parallel-group, controlled clinical trial is being conducted on 72 patients.

Settings and conduct
In this single-blind clinical trial, all patients who are candidates for elective thoracotomy surgery at Sina Hospital in Tehran will be included in the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria; Age between 18 and 70 years, Indications for Thoracotomy Exclusion criteria; Death before thoracotomy, Patients with known coagulation disorders, Uncontrolled diabetes, History of addiction, Allergy to ketamine, History of psychiatry diseases, History of seizures.

Intervention groups
In Intervention group, after induction of anesthesia before the first incision, 0.3 mg/kg intravenous ketamine is administered as a bolus, followed by intravenous infusion at a rate of 0.3 mg/kg/hour for patients. In case of postoperative pain (VAS score > 4), 2.5 mg of intravenous morphine is injected and its frequency is recorded. In Control group, at the end of the operation, epidural infusion of 0.2% ropivacaine is started in all patients at an infusion rate of 10 cc/hour. In case of postoperative pain (VAS score > 4), 2.5 mg of intravenous morphine is injected and its frequency is recorded.

Main outcome variables
The postthoracotomy pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260708070098N1**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **prospective**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date
2026-07-20, 1405/04/29

Registrant information

Name
Fatemeh Tabesh Moghadam

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6634 8500

Email address
fatemehtabesh64@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date
2027-02-20, 1405/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of epidural catheter with ketamine drip in analgesia after elective thoracotomies

Public title
Post thoracotomy pain management
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Indications for Thoracotomy Age between 18 and 70 years
Exclusion criteria:
Death before thoracotomy Patients with known coagulation disorders Uncontrolled diabetes History of addiction Allergy to ketamine History of psychiatry diseases History of seizures
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using the random permutation block method. In this method, the block sizes are 4 and 2 (in random order) and the allocation ratio is 1:1. In this way, an equal number of each treatment will be provided in each block. The random sequence will be generated by the methodologist using the sealedenvelope.com software. The random allocation list of the clusters will be available only to the design methodologist. In order to conceal the randomization process, 72 paper labels will be written with random 10-digit codes without a specific order and frame, which will be the identification number of the relevant treatment, and only the design methodologist will be aware of the relevant code. The labels will be attached to the drug packages in the order of the randomization list. The drug packages will be arranged in a box in the order of the randomization list. When the physician declares a patient eligible, the design methodologist will provide the patient with the treatment package. The design methodologist will be excluded from the rest of the study processes.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study is single-blind. The drugs used in the two groups are prepared in identical containers without name labels, in the same color and smell, and are coded. They are provided to both groups based on random allocation by the project partner, so none of the patients are aware of the treatment assigned and will not be informed until the end of the study.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Sina Hospital - Tehran University of Medical Sciences
Street address
Sina Hospital, before reaching Hassan Abad Square, Imam Khomeini Street (RA)
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2025-02-19, 1403/12/01
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1403.156

Health conditions studied

1

Description of health condition studied
Thoracotomy
ICD-10 code
S21.1
ICD-10 code description
Open wound of front wall of thorax

Primary outcomes

1

Description
Postoperative pain
Timepoint
2,4,8,12,24,48 hours postoperative
Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Systolic Blood Pressure
Timepoint
2,4,8,12,24,48 h postoperative
Method of measurement
mm/Hg

2

Description
Diaystolic Blood Pressure
Timepoint
2,4,8,12,24,48 h postoperative
Method of measurement
mm/Hg

3

Description
Diaystolic Blood Pressure
Timepoint
2,4,8,12,24,48 h postoperative
Method of measurement
Respiratory rate for min

4

Description
Heart Rate
Timepoint
2,4,8,12,24,48 h postoperative
Method of measurement
Heart Rate for 1 min

Intervention groups

1

Description
Intervention group: In this group, after induction of anesthesia before the first incision, 0.3 mg/kg intravenous ketamine is administered as a bolus, followed by intravenous infusion at a rate of 0.3 mg/kg/hour for patients. In case of postoperative pain (VAS score > 4), 2.5 mg of intravenous morphine is injected and its frequency is recorded.
Category
Treatment - Drugs

2

Description
Control group: In this group, at the end of the operation, epidural infusion of 0.2% ropivacaine is started in all patients at an infusion rate of 10 cc/hour. In case of postoperative pain (VAS score > 4), 2.5 mg of intravenous morphine is injected and its frequency is recorded.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital, Tehran University of Medical Sciences
Full name of responsible person
Dr. Matin Vahedi
Street address
Sina Hospital, before reaching Hassan Abad Square, Imam Khomeini Street (RA)
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Amir Shokri
Street address
Sina Hospital, before reaching Hassan Abad Square, Imam Khomeini Street (RA)
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hosp_sina@sina.tums.ac.ir
Web page address
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Matin Vahedi

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Fatemeh Tabesh Moghaddam

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. fatemeh tabesh Moghaddam

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
-

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available