

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+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

Diastolic Blood Pressure

Timepoint

2,4,8,12,24,48 h postoperative

Method of measurement

mm/Hg

3

Description

Diastolic 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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fatemehtabesh64@gmail.com

Web page address

<https://sinahospital.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Amir Shokri

Street address

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Email

hosp_sina@sina.tums.ac.ir

Web page address

<https://sinahospital.tums.ac.ir/vc>

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 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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Fatemeh Tabesh Moghaddam

Position

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Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Postal code

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