

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effect of dexmedetomidine injection in epidural block on analgesia in patients after thoracotomy.

#### Protocol summary

##### Study aim

The effect of dexmedetomidine injection in epidural block on analgesia in patients after thoracotomy

##### Design

This study is a double-blind, randomized, controlled clinical trial on 40 patients. Block randomization method is used for randomization.

##### Settings and conduct

First, the patient is placed in a sitting position, and an 18 gauge needle is inserted using the paramedian method and lidocaine will be injected through the needle. Then an epidural catheter is inserted through the needle. For the intervention group, ropivacaine and dexmedetomidine as a bolus are injected through an epidural catheter before surgical incision and then as an epidural infusion will be continued during surgery and up to 48 hours after surgery. For the control group, ropivacaine is injected through an epidural catheter before surgical incision and continues with an infusion of ropivacaine during surgery and up to 48 hours after surgery. This study is performed in Rasoul Akram Hospital in Tehran. In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for thoracotomy surgery, ASA physical class < or = class III  
Exclusion criteria: Treatment with alpha adrenergic antagonists  
Contraindications to epidural catheter placement  
Patients who do not have the possibility of extubation after surgery

##### Intervention groups

Intervention group: Patients who are candidates for thoracotomy surgery who use dexmedetomidine with ropivacaine for analgesia for epidural anesthesia. Control group: Patients who are candidates for thoracotomy surgery who use ropivacaine for epidural anesthesia.

#### Main outcome variables

Patient pain, adequate respiratory ventilation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181104041550N1**

Registration date: **2022-01-13, 1400/10/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-13, 1400/10/23**

Update count: **0**

##### Registration date

2022-01-13, 1400/10/23

##### Registrant information

##### Name

SaeidReza Entezary

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6651 5758

##### Email address

entezary.sr@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-22, 1400/10/01

##### Expected recruitment end date

2022-06-20, 1401/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of dexmedetomidine injection in epidural block on analgesia in patients after thoracotomy.

**Public title**

The effect of dexmedetomidine injection on analgesia in patients after chest surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Candidate patients for thoracotomy surgery ASA physical class < or = class III

**Exclusion criteria:**

Treatment with alpha adrenergic antagonists  
Contraindications to epidural catheter placement  
Patients who do not have the possibility of extubation after surgery

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Care provider
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block, we divide 4 people into groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B.

**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**

Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

8874113911

**Approval date**

2021-01-18, 1399/10/29

**Ethics committee reference number**

IR.IUMS.FMD.REC.1399.595

**Health conditions studied****1****Description of health condition studied**

Chest surgery

**ICD-10 code**

G89.22

**ICD-10 code description**

Chronic post-thoracotomy pain

**Primary outcomes****1****Description**

Patients pain rate

**Timepoint**

Up to 48 hours after surgery

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes****1****Description**

Adequate respiratory ventilation

**Timepoint**

Up to 48 hours after surgery

**Method of measurement**

Observation

## Intervention groups

### 1

#### Description

Intervention group: First, one liter of normal saline (made by Samen Pharmaceutical Company) is injected intravenously for the patient, then the patient is placed in a sitting position, and under sterile conditions, thoracic vertebrae seven to ten are identified. An 18 gauge needle is inserted using the paramedian method and 3 cc of lidocaine (made by Samen Pharmaceutical Company) will be injected through the needle. Then an epidural catheter is inserted through the needle. Then 6 mg of ropivacaine 0.1% (made by Royan Daru Pharmaceutical Company) and 1 mg of dexmedetomidine (made by Mehrdaro Pharmaceutical Company) as a bolus are injected through an epidural catheter before surgical incision and then as an epidural infusion (4 mg of ropivacaine 0.1% and 1 mg dexmedetomidine) will be continued during surgery and up to 48 hours after surgery.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: First, one liter of normal saline (made by Samen Pharmaceutical Company) is injected intravenously for the patient, then the patient is placed in a sitting position, and under sterile conditions, thoracic vertebrae seven to ten are identified. An 18 gauge needle is inserted using the paramedian method and 3 cc of lidocaine (made by Samen Pharmaceutical Company) will be injected through the needle. Then an epidural catheter is inserted through the needle. Then 6 ml of ropivacaine 0.1% (made by Royan Daru Pharmaceutical Company) is injected through an epidural catheter before surgical incision and continues with an infusion of 4 mg of ropivacaine 0.1% during surgery and up to 48 hours after surgery.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul Akram hospital

##### Full name of responsible person

SaeidReza Entezary

##### Street address

Sattar Khan St., Niayesh St., Rasoul Akram Hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

8874113911

#### Phone

+98 21 6651 5758

#### Email

entezary.sr@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Hosein Keyvani

##### Street address

Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

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##### Province

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keyvani@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

SaeidReza Entezary

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Sattar Khan St., Niayesh St., Rasoul Akram Hospital

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
SaeidReza Entezary  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Latest degree**  
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**Other areas of specialty/work**  
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## 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