Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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 an18 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, rupivacaine is injected through an epidural catheter before surgical incision and continues with an infusion of rupivacaine 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 rupivacaine for analgesia for epidural anesthesia. Control group: Patients who are candidates for thoracotomy surgery who use rupivacaine 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
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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 rupivacaine 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 rupivacaine 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
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Sponsors / Funding sources

1

Sponsor
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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
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
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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