

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of dexmedetomidine and ketamine in serratus anterior plate block in pain control of patients after thoracotomy surgery. A randomized clinical trial study

Protocol summary

Study aim

Reduction of hospitalization and treatment costs in ICU

Design

Allocation of patients into two groups of 37 people will be done by a simple random method and through sealed envelopes. They are randomly assigned to one of two groups: ketamine-ropivacaine (RK) and dexmedetomidine-ropivacaine (RD)

Settings and conduct

After obtaining the study ethics code and registering the study as an RCT, all patients referred to the Imam Khomeini Medical Training Center of Ahvaz who undergo thoracotomy surgery are evaluated in terms of the conditions of entering and exiting the study.

Participants/Inclusion and exclusion criteria

Dissatisfaction to attend the study Injection site infection Allergy to local anesthetic BMI above 40 History of drug or alcohol abuse Pregnancy or breastfeeding History of coagulation problems or use of anticoagulants History of HF and heart conduction disorders (except 1th-degree block) and AF Suffering from hepatorenal diseases History of neuropsychological diseases

Intervention groups

Ketamine-ropivacaine dexmedetomidine-ropivacaine

Main outcome variables

Patient's pain using Verbal Analog Scale (VAS), which is a subjective criterion for evaluating pain in patients and widely used in medical studies, is performed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190417043295N3**

Registration date: **2023-01-03, 1401/10/13**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-03, 1401/10/13**

Update count: **0**

Registration date

2023-01-03, 1401/10/13

Registrant information

Name

Reza Baghbanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 0168

Email address

baghbanian-r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of dexmedetomidine and ketamine in serratus anterior plate block in pain control of patients after thoracotomy surgery. A randomized clinical trial study

Public title

Comparison of dexmedetomidine and ketamine in serratus anterior plane block in pain control after

thoracotomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Physical condition with ASA class 1 and 2 Age 18 to 60 years

Exclusion criteria:

Dissatisfaction to attend the study Injection site infection Allergy to local anesthetic BMI above 40 History of drug or alcohol abuse Pregnancy or breastfeeding History of coagulation problems or use of anticoagulants History of HF and heart conduction disorders (except 1th degree block) and AF Suffering from hepatorenal diseases History of neuropsychological diseases

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Thoracotomy operations are usually performed within several months of sampling, and the required 74 patients will not undergo such an operation in the hospital at the same time. 74 sealed envelopes with cards inside that include 37 cards number 1 and 37 cards number 2 are prepared and each patient is randomly selected for the group in which they will be studied. Description of groups: 1-Prescription of ropivacaine and dexmedetomidine 2- Prescription of ropivacaine and ketamine

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Golestan Hospital Research

Street address

Iran,Golestan Ave, Golestan Hospital

City

Ahvaz

Province

Khuzestan

Postal code

15794-61357

Approval date

2022-11-01, 1401/08/10

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.117

Health conditions studied

1

Description of health condition studied

Pain control of patients after thoracotomy surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Verbal Analog Scale (VAS)

Timepoint

This criterion is rated as a continuous line, which is divided from 0-10 into equal intervals before inversion, one hour, six hours, twelve hours, twenty-four hours, and forty-eight hours later, and the patient uses it to reduce pain. He grades himself

Method of measurement

Based on the patient's self-rating of pain intensity

Secondary outcomes

1

Description

O2 Saturation

Timepoint

Before intervention , one hour, six hours, twelve hours, twenty four hours and forty eight

Method of measurement

Based on measurement with pulse oximetry

2

Description

Mean arterial pressure

Timepoint

Based on measurement

Method of measurement

mmHg

3

Description

heart beat

Timepoint

Based on measurement

Method of measurement

this The information includes body temperature, blood

pressure, heart rate, breathing rate, as well as blood oxygen saturation and amount CO₂ is the end of exhalation. Patient's pain using verbal pain index (Verbal Analog Scale); that It is a subjective criterion for evaluating pain in patients and is widely used in medical studies

4

Description

Duration of surgery

Timepoint

Based on measurement

Method of measurement

The duration of the surgery is recorded at the end of the surgery and transferred to the patient's checklist.

Intervention groups

1

Description

First, the patient is placed in the supine or lateral decubitus position and a high-frequency linear transducer is used sagittally or transversely on the midaxillary line. The transducer is slowly directed towards the back of the body to reveal the space between the latissimus dorsi and serratus anterior muscles, ribs and pleura. After prep and drape, the needle (22 gauge model Dr. J-602 made by Dr. Japan) is used (in-plane or out of plane). After aspiration, half of the surface solution is injected into the serratus anterior muscle in the depth of the latissimus dorsi muscle and the rest (the other half) in the depth of the serratus anterior muscle, and after the needle is removed, it is placed under pressure and an ice pack. In the first group, ketamine 0.5 mg/kg and 0.4 cc/kg ropivacaine 0.25% and in the second group, in addition to 0.4 cc/kg ropivacaine 0.25%, dexmedetomidine 0.5 microgram/kilogram was added.

Category

Treatment - Drugs

2

Description

The second intervention group: the second group, dexmedetomidine 0.5 mcg/kg and 0.4 cc/kg ropivacaine 0.25%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Mahbobeh Rashidi

Street address

24 metery street, east sahely highway, ahvaz

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Pain and anesthesia research center

Grant code / Reference number

PAIN-0115

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Mahbobeh Rashidi

Position

Assistant Professor of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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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

No - There is not a plan to make this available