

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of serratus anterior plate block with ropivacaine and ropivacaine-dexmedetomidine combination to reduce pain in patients after thoracotomy surgery

Protocol summary

Study aim

Determining the effective drug and reducing the use of narcotic drugs

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

Patients undergoing thoracotomy surgery in Imam Khomeini Hospital, Ahvaz Age 18 to 60 years; Class I or II physical condition Patients are randomly assigned to one of the two groups of ropivacaine (R) or ropivacaine-dexmedetomidine (RD). The grouping of patients is random and the patient and the person in charge of registering the patient's information are not aware of the patient's allocation group. Information is entered into the checklist, which includes name, age, gender, height and weight, BMI, pain score, duration of operation, length of stay in ICU, time of walking in ICU and amount of narcotics a

Participants/Inclusion and exclusion criteria

The criteria for entering the study are: Age 18 to 60 years; Class I or II physical status according to the criteria of the Association of Anesthesiologists (ASA); body mass index (BMI) less than 40; No history of drug or alcohol abuse; absence of pregnancy or breastfeeding; No history of coagulation problems or use of anticoagulants; jump fraction higher than 30%; No history of conduction heart block; absence of acute or chronic hepatitis; lack of history of psychiatric diseases; No need for complementary renal treatments or a history of kidney failure; Absence of neuropathy: Exclusion criteria: sensitivity to study drugs and unwillingness of patients to cooperate.

Intervention groups

ropivacaine (R)-ropivacaine-dexmedetomidine(RD)

Main outcome variables

vagus nerve stimulation (VNS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221222056890N1**

Registration date: **2024-02-15, 1402/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-15, 1402/11/26**

Update count: **0**

Registration date

2024-02-15, 1402/11/26

Registrant information

Name

Mahbobeh Rashidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 916 616 8655

Email address

rashidi-m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-11, 1402/11/22

Expected recruitment end date

2024-03-10, 1402/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of serratus anterior plate block with ropivacaine and ropivacaine-dexmedetomidine combination to reduce pain in patients after thoracotomy surgery

Public title

Comparison of anterior serratus plate block with ropivacaine and ropivacaine-dexmedetomidine combination for pain reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years; Class I or II physical status according to the criteria of the Association of Anesthesiologists (ASA); body mass index (BMI) less than 40; No history of drug or alcohol abuse; absence of pregnancy or breastfeeding; No history of coagulation problems or use of anticoagulants; jump fraction higher than 30%; No history of conduction heart block (except first degree heart block and controlled atrial fibrillation); absence of acute or chronic hepatitis; lack of history of psychiatric diseases; No need for complementary renal treatments or a history of kidney failure; No neuropathy

Exclusion criteria:

Allergy to study drugs and patients' unwillingness to cooperate.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of patients is done in random order in this way, which is done using the randomization table. The information is entered into the checklist. The checklists are already numbered by the statistical consultant, and this numbering is the basis for the allocation of patients, but the allocation of numbers to groups will not be revealed until the results are analyzed

Blinding (investigator's opinion)

Double blinded

Blinding description

In this way, the patient and the specialist doctor are not aware of the type of medicine. Allocation of patients is done in random order in this way, which is done using the randomization table. The patient and the person responsible for registering the patient's information are unaware of the patient's diagnostic group. The information is entered into the checklist. Checklists are already numbered by a statistical consultant and this

numbering is the basis of patient allocation, but the allocation of numbers to groups will not be revealed until the results are analyzed. The person responsible for injecting the drug is aware of the injected drug, but in the collection process And data analysis does not participate.

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

Golestan Ave, Golestan Hospital

City

ahvaz

Province

Khouzestan

Postal code

1579461357

Approval date

2024-02-07, 1402/11/18

Ethics committee reference number

IR.AJUMS.REC.1402.615

Health conditions studied

1

Description of health condition studied

Pain reduction in patients after thoracotomy surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Verbal Numeric Scale (VNS)

Timepoint

The patient expresses her/his pain as a number between 0 and 10, where 0 means no pain and 10 is the maximum pain.

Method of measurement

Based on the patient's expression of pain intensity

Secondary outcomes

1

Description

ICU admission

Timepoint

2-6-12-24-48

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: 0.4 cc/kg of 0.2% Ropivacaine solution

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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6193673166

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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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

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

Ph.D.

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

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

Ahvaz University of Medical Sciences

Full name of responsible person

Mahbobeh Rashidi

Position

Assistant Professor of Anesthesiology

Latest degree

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Other areas of specialty/work

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