

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of ultrasound guided intercostal nerve block with ropivacaine against Ropivacaine and Dexmedetomidine on reduction of postoperative pain in patients undergoing thoracotomy: a randomized clinical trial

Protocol summary

Study aim

The aim of this study is to assess the effect of adding Dexmedetomidine to Ropivacaine on pain after thoracotomy.

Design

Double-blind clinical trial, with parallel, randomized groups, phase 3 on 74 patients, randomization using www.Randomizer.org service

Settings and conduct

Thoracotomy patients in Ahvaz Imam Khomeini Hospital undergo intercostal nerve block. Physician in charge of injection, the patients and the outcome assessors are blinded to the study by using a transparent label coded syringe. only the physician in charge of preparing the syringe is aware of the contents.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18 to 60 years, American Society of Anesthesiologists physical status Class I, II or III, Body Mass Index less than 40, No history of substance or alcohol abuse, No pregnancy or breastfeeding, No history of coagulation problems or use of anticoagulants, Ejection fraction above 30%, No history of cardiac conduction block (except for first-degree cardiac block and controlled atrial fibrillation), No acute or chronic hepatitis, No history of psychiatric illness, No need for renal supplementation or a history of kidney failure, Absence of Neuropathy, Exclusion Criteria: Hypersensitivity to study medication

Intervention groups

At the end of thoracotomy, after extubation and hemodynamic stability, the intercostal nerve block is done using a code labeled transparent syringe under ultrasound guidance (M7, MindRay China) by a Pain Fellowship. the intercostal nerve block is done one space above and two spaces below the surgical incision site. Control Group: 5 cc Ropivacaine (Molteni Farmaceutici, Italy) 0.25% is injected in the three spaces. Intervention

Group: in Addition to Ropivacaine (5cc, 0.25%), Dexmedetomidine (Exir Pharmaceutical Co., Iran), 0.5 mcg/kg is injected, divided between the three spaces.

Main outcome variables

Post operative Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190107042264N2**

Registration date: **2020-11-27, 1399/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-27, 1399/09/07**

Update count: **0**

Registration date

2020-11-27, 1399/09/07

Registrant information

Name

Ehsan Hedayatinejad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-02-17, 1399/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ultrasound guided intercostal nerve block with ropivacaine against Ropivacaine and Dexmedetomidine on reduction of postoperative pain in patients undergoing thoracotomy: a randomized clinical trial

Public title

Comparison of Ropivacaine against Ropivacaine and Dexmedetomidine on postoperative pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

American Society of Anesthesiologists physical status Class I, II or III Body Mass Index less than 40 No History of Alcohol or Drug abuse Not pregnant/Breastfeeding No history of coagulation problems or use of anticoagulants Ejection Fraction more than 30% No history of cardiac conduction block (except for first-degree cardiac block and controlled atrial fibrillation) No acute or chronic hepatitis No history of psychiatric illness No Need for renal supplementation or a history of kidney failure No Known Neuropathy

Exclusion criteria:

Hypersensitivity to study drugs

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **74****Randomization (investigator's opinion)**

Randomized

Randomization description

Using Research Randomizer(freely available at www.randomizer.org) 74 random numbers are generated. this unsorted series of numbers are then used to assign coded drugs to patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

After obtaining a series of unsorted random numbers from the website, the numbers are used to divide consecutive patients into two groups. This data is then given to the anesthesiologist in charge of the study. This specialist, who is aware of patient assignments, Prepares

study medications for injection in a transparent syringe, labeled with the code of each patient and provides them to a second anesthesiologist. this second anesthesiologist, who is unaware of the contents of the syringe then puts patients, who are unaware of the used medications, under intercostal nerve block. Patients are then transferred to the intensive care unit and monitored. Here, the patient data is collected in coded forms by the data collection team, who are unaware of patient assignment to groups. This information is provided to the statistical analyzer in numbered forms along with the information related to the assignment to the groups for statistical analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Esfand Street, Golestan, Ahvaz, Iran

City

Ahvaz

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Khouzestan

Postal code

1579461357

Approval date

2020-02-10, 1398/11/21

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1398.041

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

Post Thoracotomy Pain

ICD-10 code

G89.12

ICD-10 code description

Acute post-thoracotomy pain

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

Pain

Timepoint

Immediately after return to Surgical Intensive Care Unit (ICU) from post surgical recovery, then again after 6, 12, 24 and 48 hours from return to surgical ICU

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Systolic Blood Pressure

Timepoint

Immediately after return to Surgical Intensive Care Unit (ICU) from post surgical recovery, then again after 6, 12, 24 and 48 hours from return to surgical ICU

Method of measurement

Aneroid Sphygmomanometer

2

Description

Pulse Rate

Timepoint

Immediately after return to Surgical Intensive Care Unit (ICU) from post surgical recovery, then again after 6, 12, 24 and 48 hours from return to surgical ICU

Method of measurement

Pulse Oxymeter

3

Description

Oxygen Saturation

Timepoint

Immediately after return to Surgical Intensive Care Unit (ICU) from post surgical recovery, then again after 6, 12, 24 and 48 hours from return to surgical ICU

Method of measurement

Pulse Oxymeter

4

Description

Diastolic Blood Pressure

Timepoint

Immediately after return to Surgical Intensive Care Unit (ICU) from post surgical recovery, then again after 6, 12, 24 and 48 hours from return to surgical ICU

Method of measurement

Aneroid Sphygmomanometer

Intervention groups

1

Description

Intervention group: At the end of the thoracotomy operation, after extubation in recovery and after hemodynamic stability, Intercostal nerve block under ultrasound guidance (model: M7 made by MindRay

company, China) is performed by Pain Fellowship. The intercostal block is performed in supine position and along the posterior axillary line. The ultrasound probe is placed sagittally and after identifying the External, Internal and innermost intercostal muscles, using the Quinke Spinal Needle No. 22 (made by Dr. Japan, Japan), Injection for the intercostal nerve block is done in one space above and two spaces below the surgical incision site. In the Intervention Group Ropivacaine (5 cc of 0.25% solution; made by Molteni Farmaceutici, Italy) plus dexmedetomidine 0.5 mcg per kilogram body weight (Medonex, Exir Pharmaceutical Co., Iran) is used, Divided between the three spaces.

Category

Treatment - Drugs

2

Description

Control group: At the end of thoracotomy and after extubation and hemodynamic stability, in the recovery room, intercostal nerve block under ultrasound guidance (model: M-7 made by Mindray, China) is performed by pain fellowship. The intercostal block is performed in the supine position and along the posterior axillary line. The ultrasound probe is placed sagittally and after identifying the External, Internal and innermost intercostal muscles, using the Quinke Spinal Needle No. 22 (made by Dr. Japan, Japan) Injection for the intercostal nerve block is done in one space above and two spaces below the surgical incision site. In the control group, Ropivacaine (5 cc of 0.25% solution; made by Molteni Farmaceutici, Italy), is used, Divided between the three spaces.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Teaching Hospital

Full name of responsible person

Kamran Mahmoudi

Street address

Golestan Teaching Hospital - Farvardin St - Golestan

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Web page address

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2

Recruitment center

Name of recruitment center

Imam Khomeini Teaching Hospital

Full name of responsible person

Mahbobeh Rashidi

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Imam Khomeini Hospital - Shahid Ahvazian Street -
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

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Vice Chancellory of Research and Technology, Central
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Web page address

<https://vchresearch.ajums.ac.ir>

Grant name**Grant code / Reference number**

PAIN-9846

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

Kamran Mahmoudi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Kamran Mahmoudi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Kamran Mahmoudi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Email

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