

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The efficacy of serratus anterior plane block with different dose of dexmedetomidine for patients with tube thoracostomy

Protocol summary

Study aim

Using the results and information of this study to control the patient's pain after removing the chest tube

Design

Randomized, superiority, parallel group trial with double blinded outcome assessment. Randomization is analyzed with SPSS software. there will be 50 samples from patients that refer to goletan or imam hospital of ahvaz.

Settings and conduct

The study will be conducted on the patients who visited the ICU center of Golestan and Imam Ahvaz hospitals in 2011-02. During the study, the anesthesia resident prepares the medicine and the fellowship doctor injects the pain medicine to the patients. The responsible student completes the relevant questionnaire. Patients, anesthesiology resident, pain fellowship doctor and student do not know which drug is injected into which patient.

Participants/Inclusion and exclusion criteria

Admission: age 18 to 60 years, physical condition, body mass index less than 40 kg/m², no history of drug or alcohol abuse, no pregnancy or breastfeeding, no history of coagulopathy or use of anticoagulants, mutation fraction above 30%, no history of block cardiac conduction, consciousness level above 14, no hepatitis, no history of psychiatric disease No need for complementary renal treatment, no neuropathy Failure to enter: sensitivity to the study drugs and unwillingness of patients to cooperate

Intervention groups

In both groups, ropivacaine is stable at 0.4 cc/kg of 0.2% solution. In group D1, 0.5 micrograms/kg of dexmedetomidine of body weight and in group D2, 1 microgram/kg of dexmedetomidine of body weight was added to the ropivacaine solution and injected according to the mentioned method.

Main outcome variables

groups of study, pain score, heart rate, systolic blood pressure, diastolic blood pressure, amount of narcotic

drug use, oxygen saturation, duration of walking, duration of stay in ICU, time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230213057405N1**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **prospective**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

Registration date

2023-03-14, 1401/12/23

Registrant information

Name

Danial jazayeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 224 0138

Email address

jazayeri.sd@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of serratus anterior plane block with different dose of dexmedetomidine for patients with tube thoracostomy

Public title

The efficacy of serratus anterior plane block with different dose of dexmedetomidine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient consent to enter the study physical condition class I-II according to the standards of the Association of Anesthesiologists body mass index (BMI) less than 40 kg/m² no pregnancy or breastfeeding no history of coagulopathy or the use of anticoagulants Ejection fraction higher than 30%, no history of conductive heart block (except for first degree heart block and controlled atrial fibrillation) the patient's level of consciousness should be above 14 no acute or chronic hepatitis no history of psychiatric disease no need for complementary Renal treatment or history of kidney failure and no neuropathy no history of drug or alcohol abuse

Exclusion criteria:

Allergy to the studied drugs unwillingness of patients to cooperate

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will divide into two groups with simple randomization. in order to randomization, two groups of closed envelope will be given to them. one group is D1 and another one is D2. number of two groups is equal.the patient picks up an envelope randomly and enters at his/her group. anesthesiology resident will prepare drugs and trial will be operated double blinded.

Blinding (investigator's opinion)

Double blinded

Blinding description

in this trial, anesthesiology resident will prepare the drug and anesthesiologist doctor(fellowship of pain) will insert the drug. medial intern fill the questionnaire. the patients, anesthesiology resident, anesthesiologist doctor and medial intern will not know which drug is given to which patient. so, the trial will be double_blinded.

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

Farvardin Street, Golestan

City

ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Approval date

2022-12-13, 1401/09/22

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.158

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

pain in patients with tube thoracostomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Study groups, pain score, heart rate, systolic blood pressure, diastolic blood pressure, amount of narcotic drug use, oxygen saturation, duration of walking, duration of stay in ICU

Timepoint

nominal, distance, relative, ratio (in mm Hg), ratio (in mm Hg), ratio (in mg/k), ratio (in percentage), ratio (in minutes), ratio (in minutes)

Method of measurement

According to the dose of dexmedetomidine, they are divided into two groups, 0.5 and 1. Based on the criteria, VNS describes the pain between numbers and 10, the number of heartbeats in one minute, systolic blood pressure measured by a sphygmomanometer, diastolic blood pressure measured by a sphygmomanometer, the amount of drug use. Narcotics to control the patient's pain, oxygen saturation percentage using pulse oximeter, time (using clock measurement), time (using clock measurement)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group one that get 0.5 microgram per kg dexmedetomidine

Category

Treatment - Drugs

2

Description

Intervention group: group two that get 1 microgram per kg dexmedetomidine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Kamran Mahmoodi

Street address

24 meter street

City

AHVAZ

Province

Khouzestan

Postal code

۶۱۹۳۶۷۳۱۶۶

Phone

+98 61 3311 0000

Fax

Email

himam@ajums.ac.ir

Web page address

2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Kamran Mahmoodi

Street address

Golestan - Farvardin Boulevard - in front of Iqbal Street

City

ahvaz

Province

Khouzestan

Postal code

1579461357

Phone

+98 61 3320 4501

Fax

+98 61 3320 4516

Email

golestanhospital@ajums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Farvardin Street, Golestan

City

ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 61 3311 0000

Email

info@ajums.ac.ir

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

Kamran Mahmoodi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Farvardin Street, Golestan

City
ahvaz
Province
Khouzestan
Postal code
15794 - 61357
Phone
+98 61 3311 0000
Email
mahmoudi-k@ajums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Kamran Mahmoodi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Farvardin Street, Golestan
City
ahvaz
Province
Khouzestan
Postal code
15794 - 61357
Phone
+98 61 3311 0000
Email
mahmoudi-k@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Kamran Mahmoodi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Farvardin Street, Golestan
City
ahvaz
Province
Khouzestan
Postal code
15794 - 61357
Phone
+98 61 3311 0000
Email
mahmoudi-k@ajums.ac.ir

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