

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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/m<sup>2</sup>, 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/m<sup>2</sup> 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

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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

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##### Province

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1579461357

##### Phone

+98 61 3320 4501

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##### 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

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##### Province

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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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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Ahvaz University of Medical Sciences

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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