

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparison study of continuous serratus anterior plane block and thoracic epidural block in post thoracotomy analgesia

#### Protocol summary

##### Study aim

Comparison study of continuous serratus anterior plane block and thoracic epidural block in post thoracotomy analgesia

##### Design

Clinical trial with intervention and control groups, 40 patients sample size, Trial phase 2-3. Simple randomization based on random numbers table.

##### Settings and conduct

40 participants who meet inclusion criteria among candidates referred to the Masih Daneshvari hospital in 2019 were divided to continuous anterior serratus block or epidural thoracic continuous block.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate for continuous anterior serratus block / persistent thoracic epidural block; Age 18 and above; Patients with satisfaction to participate in the study  
Exclusion criteria: Contraindication of any continuous anterior / epidural thoracic continuous block; Chronic thoracic pain; Drug and Alcohol Abuse; Coagulopathy; Patients dissatisfied with participation in the study

##### Intervention groups

Intervention group: The ultrasound probe is placed in the midclavicular region of the chest at the sagittal surface. After determining the fifth midaxillary rib, the needle is inserted to a depth of 1-2 cm. After fixation of the epidural catheter in the anterior of the serratus muscle, first 10 ml of 0.25% marcain is injected and then 5 ml of solution contains 0.1% marcine is infused. Control group: The epidural catheter is fixed in the T7-8 space. The injectable drugs are similar to the intervention group.

##### Main outcome variables

Pain Level

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20131124015515N9**

Registration date: **2019-10-27, 1398/08/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-27, 1398/08/05**

Update count: **0**

##### Registration date

2019-10-27, 1398/08/05

#### Registrant information

##### Name

Masoud Hashemi

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2261 2252

##### Email address

dr.hashemi@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2019-10-21, 1398/07/29

#### Expected recruitment end date

2019-12-20, 1398/09/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison study of continuous serratus anterior plane block and thoracic epidural block in post thoracotomy analgesia

**Public title**

Comparison of postoperative thoracotomy analgesia with continuous serratus block and epidural thoracic block

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 and above Patients candidate for continuous anterior serratus block / persistent thoracic epidural block Patients with satisfaction to participate in the study

**Exclusion criteria:**

Contraindication of any continuous anterior / epidural thoracic continuous block Chronic thoracic pain Drug and Alcohol Abuse Coagulopathy Patients dissatisfied with participation in the study

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization based on random numbers table. In this way, we put a set of numbers in a completely random order without any pattern or order, set the table numbers to read from above. For intervention group we consider even numbers and for control group we consider individual numbers. Then we place one of the numbers up and down, register the number and assign it to one of the intervention or control groups.

**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 of Shahid Beheshti University of Medical Sciences

**Street address**

Tabnak St., Tehran, Tehran, Iran, Islamic Republic Of

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2017-10-27, 1396/08/05

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1396.844

**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 level

**Timepoint**

2, 4, 6, 8, 24 and 48 hours after block

**Method of measurement**

Visual analog scale (VAS) (0 None; 1-3 Mild; 4-7 Moderate; 8-10 Severe)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The ultrasound probe is placed in the midclavicular region of the chest at the sagittal surface. After determining the fifth midaxillary rib, the needle is inserted to a depth of 1-2 cm. After fixation of the epidural catheter in the anterior of the serratus muscle, first 10 ml of 0.25% marcain is injected and then 5 ml of solution contains 0.1% marcine is infused.

**Category**

Treatment - Devices

**2****Description**

Control group: The epidural catheter is placed in the T7-8 space. The injectable drugs are similar to the intervention group.

**Category**

Treatment - Devices

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Masih Daneshvari hospital

**Full name of responsible person**

Masoud Hashemi MD

**Street address**

Darabad, Shahid Bahonar (Niavaran) Street

**City**

Tehran

**Province**

Tehran

**Postal code**

19556

**Phone**

+98 21 2712 3000

**Email**

dr.hashemi@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi MD.

**Street address**

Shahid Arabi st., Yaman St., Shahid Chamran Expressway

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2243 9781

**Email**

zarghi@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Masoud Hashemi MD.

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Akhtar hospital, Sharifi Manesh st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1964714953

**Phone**

+98 21 2261 2252

**Email**

dr.hashemi@sbmu.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Masoud Hashemi MD.

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## Person responsible for updating data

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The whole data can be shared after unidentifiable people.

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Only available to scholars working in academic and academic institutions

**Under which criteria data/document could be used**

Employed in research centers

**From where data/document is obtainable**

Person responsible for scientific inquiries

**What processes are involved for a request to access data/document**

Send email to person responsible for scientific inquiries

**Comments**