Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the role of Serratus anterior plane block to manage post-thoracotomy pain: a randomized controlled trial, Phase II

Protocol summary

Study aim

investigate the effect of Serratus anterior plane block to manage post-thoracotomy pain

Design

This is a randomized, double-blind clinical trial (phase II) with parallel groups that is performed on 120 patients who are candidate for thoracotomy. Randomization is conducted by using online block randomization software. The severity of post-surgical pain is evaluated by using Visual analog scale (VAS).

Settings and conduct

This study is conducted in the surgery department of Shariati Hospital in Tehran. All patients receive IV morphine, 5 mg every 6 hours, IV Apotel 1 gr every 8 hours, and Diclofenac suppository every 8 hours for pain control. In addition to these treatments, the intervention group undergoes Serratus anterior plane block before closing the surgical incision, So, the patient is blind about the study group. That researcher who evaluates the outcome, dose not participates in randomization and surgery procedure so is blind about the patient group too.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age candidate for thoracotomy, who met the American Society of Anesthesiology (ASA) Class I-II classification criteria. Participants who has met any of the following criteria were excluded from the study: Participants who refused to cooperate History of sensitivity to local anesthesia Patients with American Society of Anesthesiologists (ASA) class IV-V criteria. Unstable hemodynamic (systolic blood pressure <90 mm-Hg or mean arterial pressure <60 mm-Hg) Coagulation disorders Surgical site infection

Intervention groups

Control: control pain with opioids, NSAIDs or acetaminophen Intervention: control pain with opioids, NSAIDs or acetaminophen and, they will undergo Serratus anterior plane block.

Main outcome variables

Post-thoracotomy pain/ Visual analog scale (VAS) is used to evaluate this outcome in 6, 12 and 24 hours after operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230416057931N1**
Registration date: **2023-10-02, 1402/07/10**
Registration timing: **retrospective**

Last update: **2023-10-02, 1402/07/10**
Update count: **0**

Registration date

2023-10-02, 1402/07/10

Registrant information

Name

Yaser Ftouni

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 910 363 4196

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yaser.ftouni91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-18, 1402/04/27

Expected recruitment end date

2023-09-18, 1402/06/27

Actual recruitment start date

2023-07-20, 1402/04/29

Actual recruitment end date

2023-09-11, 1402/06/20

Trial completion date

2023-09-16, 1402/06/25

Scientific title

Evaluating the role of Serratus anterior plane block to manage post-thoracotomy pain: a randomized controlled trial, Phase II

Public title

The role of Serratus anterior plane block to manage post-thoracotomy pain: a randomized controlled trial, Phase II

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with American Society of Anesthesiologists class (ASA) class I–II criteria

Exclusion criteria:

Participants who refused to cooperate History hypersensitivity to local anesthesia Patients with American Society of Anesthesiologists class (ASA) class IV-V criteria Unstable hemodynamic (systolic blood pressure <90 mm-Hg or mean arterial pressure< 60 mm-Hg) Coagulation disorders Surgery site infection

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study randomization performs based on the blocked randomization method. Information such as the number of study groups (2 main groups: intervention (for example A) and control (for example (B), block size (a multiple of the number of groups that will be chosen in this study to reduce the complexity of the work, size 4) and the total number of patients (sample size 60 people), were enter into the online software machines specific for this calculation (for example available at https://www.sealedenvelope.com/simple-randomiser/v1/lists) and according to the codes that it is obtained by the final analysis (including the number of specific groups of 4, which will be 17 groups here) (for example (group B 1, 4, 1, each of the patients being studied is given a specific code respectively. Blocking is usually used in order to create a balance in the number of samples assigned to each of the studied groups. In this method, equal blocking will be used. In this way, the samples are randomized in two groups as much as possible.

Blinding (investigator's opinion)

Double blinded

Blinding description

All steps of group assignment are done by a researcher who does not have a role in the data collection, and the data will be recorded by a researcher who is blind to the group allocation and was not involved or present during the surgery, and will not know about the sample group until after the data analysis. Patients do not know which group they are in and the intervention is done before the patient regains consciousness.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd., Qods St., Tehran University of Medical Sciences

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Province

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Postal code

1416634793

Approval date

2023-06-15, 1402/03/25

Ethics committee reference number

IR.TUMS.SHARIATI.REC.1402.038

Health conditions studied

1

Description of health condition studied

Serratus anterior plane block

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post-thoracotomy pain

Timepoint

Pain severity score 6, 12 and 24 hours after surgery

Method of measurement

Visual analog scale for pain (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Yaser Ftouni
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Tehran, North Kargar St., Jalal Al Ahmad HWY
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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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
Tehran 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
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Latest degree

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Other areas of specialty/work

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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

No - There is not 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