

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of Erector Spinae Plane Block in comparison with Intercostal Block in patients in need of chest tube fixation.

Protocol summary

Study aim

Comparing the effects of Erector Spinae Block and Intercostal block on the level of analgesia in patients undergoing chest tube placement.

Design

A clinical trial with a control group, with parallel groups. Two blind strains. Phase 3 was randomized on 60 patients and balanced block was used for randomization.

Settings and conduct

It is an intervention study and a clinical trial type. The sample size is 60 people. Patients who need to have a chest tube implanted in the operating room of Shahid Beheshti Hospital, Qom, and after obtaining written consent, are divided into two groups by randomization using the block randomization method: the first group includes 30 patients who undergo intercostal block. The second group of 30 patients will undergo erector spinae block.

Participants/Inclusion and exclusion criteria

Admission requirements: age 18-50 years, ASA Class I-II
Conditions of non-entry: emergency cases, ASA Class III and more, history of drug allergy, sensitivity to local anesthetic, psychotic disease, drug addiction, coagulation disorder, local skin infection, chronic use of painkillers and NSAID.

Intervention groups

Intervention group (E) under Erector Spinae block: After obtaining consent for nerve block, eligible people will be blocked under aseptic conditions under ultrasound guidance by random sampling before chest intubation. They receive 15 cc of bupivacaine 0.5% at T5 level.
Control group (I) under intercostal block: after obtaining consent for nerve block, eligible people are blocked under aseptic conditions under ultrasound guidance as random sampling before chest intubation. 15 cc of bupivacaine 0.5% is equally divided into three levels: T4, T5-T6.

Main outcome variables

Pain level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240421061548N1**

Registration date: **2024-06-18, 1403/03/29**

Registration timing: **prospective**

Last update: **2024-06-18, 1403/03/29**

Update count: **0**

Registration date

2024-06-18, 1403/03/29

Registrant information

Name

MOHAMMAD HASAN YOUSEFI NAJAF ABADI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3770 3971

Email address

dr.yousefi.ir@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of Erector Spinae Plane Block in comparison with Intercostal Block in patients in need of chest tube fixation.

Public title

Analgesia of patients undergoing chest intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-50 years ASA Class I - II

Exclusion criteria:

Emergency cases ASA Class III and above History of drug allergy Sensitivity to local anesthetics Psychotic disease Drug addiction Coagulation disorder Local skin infection Chronic use of painkillers and NSAIDs

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to intervention and control groups using block randomized method. The link "<https://www.sealedenvelope.com/simple-randomiser/v1/lists>" will be used for block randomization. For this purpose, the target number of samples (60 samples), number of groups (two groups A and B) and number of blocks (4) will be entered and the system will provide the researcher with a list of 4 blocks. Based on the output list, it will be determined in which group the patients who enter the study should be placed in order. Items A represent the intervention group and items B represent the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Based on the block randomization method, patients will be divided into two control and intervention groups of 30 people. In a group of anesthesiologists who will not know the type of research, they will put the patients under one of the nerve block methods based on the sealed envelope in which the type of block is specified. The principal investigator will not know which patient is receiving which block. The patient and the person filling the questionnaire do not know the type of block.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Qom University of Medical Sciences

Street address

No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd

City

Qom

Province

Ghoush

Postal code

3719964797

Approval date

2023-06-26, 1402/04/05

Ethics committee reference number

IR.MUQ.REC.1402.064

Health conditions studied

1

Description of health condition studied

Local anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

Pain level

Timepoint

Before, during and after the chest tube insertion

Method of measurement

Patient's pain level based on Visual Analogue Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group (E) under Erector Spinae block: includes 30 patients who, after obtaining consent for nerve block, eligible people, are blocked under aseptic conditions under ultrasound guidance as a random sampling before chest intubation. They receive 15 cc of bupivacaine 0.5% at T5 level.

Category

Treatment - Drugs

2**Description**

Control group ; under intercostal block: including 30 patients, after obtaining consent for nerve block, eligible people are randomly sampled before chest intubation, under aseptic conditions under ultrasound guidance. 15 cc of bupivacaine 0.5% is equally divided into three levels: T4, T5-T6.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Beheshti Hospital

Full name of responsible person

Mohamad Hasan Yousefi Najaf Abadi

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Beheshti Hospital, Beheshti Blvd, Qom, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

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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

Ghoum 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**

Ghoum University of Medical Sciences

Full name of responsible person

Mohamad Hasan Yousefi Najaf Abadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

Anesthesiology

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Province

Ghoum

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable