Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 25 3770 3971

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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
Ghoum
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Rahim Aali
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No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd
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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
Anesthesiology
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Other areas of specialty/work
Anesthesiology

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City
Qom

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