

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intercostal nerve block and local anesthesia in tube thoracostomy procedure pain

Protocol summary

Study aim

Comparison of intercostal nerve block and local anesthesia in tube thoracostomy procedure pain

Design

Two arm parallel group randomised trial without blinding on 64 patients who randomised with random number table

Settings and conduct

Hospitalized patient in Kashan Shahid Beheshti hospital who need thoracostomy randomized in two group. the first group were go under thoracostomy prosedure with local anesthesia and the other group with intercostal nerve block. we use 0.5% Bupivacaine for anesthesia in two groups. Intraoperative and postoperative pain after thoracostomy tube were documented and analyzed

Participants/Inclusion and exclusion criteria

Inclusion criteria: Established pleural effusion , Hemothorax or pneumothorax Age above 18 and below 75 years old GCS > 13 Exclusion criteria : Drug addiction Traumatic patient

Intervention groups

In first group after intercostal nerve block, thoracostomy tube inserted in second group after local anesthesia thoracostomy tube inserted

Main outcome variables

Intraoperative and postoperative pain ; Analgesic use in 24 hours after the procedure (Opioid and non-opioid)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200901048584N1**

Registration date: **2020-12-30, 1399/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-30, 1399/10/10**

Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

mohammad hasan izadian

Name of organization / entity

Country

Iran (Islamic Republic of)

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izadian_mh@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intercostal nerve block and local anesthesia in tube thoracostomy procedure pain

Public title

Comparison of intercostal nerve block and local anesthesia in tube thoracostomy procedure pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Glasgow score > 13 Pleural effusion , Hemothorax or

Pneumothorax
Exclusion criteria:
Drug addiction Opioid analgesics Trauma patients

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
To select patients for either intercostal or local anesthesia approach, simple randomization method is considered. For the former selected even numbers and for the latter odd numbers is regarded respectively. The number would be randomly placed from 01 to 64 in a table. The thoracostomy tube inserting procedure is then identical across the classic approach.

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
Faculty of Medicine & Faculty of Dentistry- Kashan
University of Medical Sciences

Street address
Qotbe ravandi Blvd

City
Kashan

Province
Isfahan

Postal code
8715985191

Approval date
2020-07-27, 1399/05/06

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.072

Health conditions studied

1

Description of health condition studied
toracostomy

ICD-10 code
J90

ICD-10 code description
Pleural effusion, not elsewhere classified

Primary outcomes

1

Description
Intraoperative and postoperative pain in thoracostomy insertion

Timepoint
Evaluation of intraoperative pain and postoperative pain in 3 , 6 , 12 , 24 hour after thoracostomy tube insertion

Method of measurement
Visual Analogue Scale

Secondary outcomes
empty

Intervention groups

1

Description
First Intervention group: Intercostal nerve block performed with totally 15 ml of 0.5% bupivacaine (produced in Astrazeneca company) . intraoperative and postoperative pain evaluate with Visual Analogue Scale .

Category
Other

2

Description
Second Intervention group: Local Anesthesia performed with maximum 35 ml of 0.5% bupivacaine (produced in Astrazeneca company) . intraoperative and postoperative pain evaluate with Visual Analogue Scale

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti hospital

Full name of responsible person
Mohammad Hasan Izadian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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<http://research.kaums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Mohammad Hasan Izadian
Position
General surgery resident
Latest degree
Medical doctor
Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

this only available for people working in academic institutions

Under which criteria data/document could be used

no criteria

From where data/document is obtainable

Mohammad Hasan Izadian Mh.izadian@gmail.com
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What processes are involved for a request to access data/document

just send an email for me

Comments