

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Epidural, Sub pleural, Inter pleural and Incisional catheter placement on post Lateral thorachotoy pain control

Protocol summary

Summary

Post operative pain management in thoracic surgery is necessary to avoid complications. In some cases that have no possibility of epidural catheter insertion, it is extremely important to determine other effective regional methods according the origin of acute pain to prevent post operative pain. Therefore, comparative effectiveness of Epidural, Intrapleural, sub pleural and incisional catheter insertion can evaluate quality and quantity of pain control, complications and drug consumption to introduce the appropriate methods for pain control after lateral Thoracotomy. Numbers of samples (120 patients) are randomly divided into equal four groups. In group (A) epidural catheter at the level of 6 T -8T is placed and 10milliliter bupivacaine 0.25% as bolus dose administered. Induction of anesthesia with Fentanyl, Midazolam, Propofol, Cisatracurium is performed. Maintenance with Propofol and Remifentanyl (TIVA) continued. At the end of surgery muscle relaxant reversed and patients extubated. Then catheter attached to the Autofuser pump by rate of 2 milliliter per hours Bupivacaine 0.25% infusion. After awaking, the patient transferred to the ICU .Pain score and Opioid (Morphine or Petteidin) needs are recorded since 2 - 6 - 12 - 24 and 48 hours in post operative period. In group (B), instead of epidural catheter, sub pleural (Para Vertebral) catheter is placed at the level of (6T-8T) and 10 milliliter bupivacaine 0.25 % as bolus is injected. Induction and maintenance of Anesthesia are the same; at the end of surgery muscle relaxant reversed and patient extubated. Then catheter attached to the Autofuser pump by the same rate infusion. After awaking, recording protocol is the same above. In group C catheter located within the pleura (special technique) at the level of (6T-8T) and 10 milliliter Bupivacaine 0.25 % as bolus injected. Induction and maintenance of Anesthesia are the same; at the end of surgery muscle relaxant reversed and patient are extubated. Then catheter attached to the Autofuser pump by the same rate infusion. After awaking,

recording protocol is the same above. In group D, Bupivacaine 0.25% (10 milliliter) infiltrated to the site of surgery before incision then Induction and maintenance of Anesthesia is performed as the same above, at the end of surgery incisional catheter is placed by surgeon then sutured and dressed. At last catheter attached to the Autofuser pump by the same rate infusion. After awaking, recording protocol is the same above. After collecting information, for parametric data; Independent T-test and for non parametric data; Mann-Whitney chi - square and Fisher exact test, analysis will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012021772N4**
Registration date: **2011-01-01, 1389/10/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-01-01, 1389/10/11

Registrant information

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Dawood Aghamohammadi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical

Sciences

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Epidural, Sub pleural, Inter pleural and Incisional catheter placement on post Lateral thorachotoy pain control

Public title

post operative pain control

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria 1-ASA II-III 2-20-60 years of old 3-needs lateral thoracotomy Exclusion Criteria 1- couaglopathy 2- drug sensitivity 3-patients avoidance 4-addiction 5- bilateral thoracotomy 6-operation time more than 3 hours 7-EF less than 40% 8-transfusion more than 4 unit 9- FEV less than 1L 10-history of previous thoracotomy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of Vice chancellor for

research, Tabriz University of Medical Sciences

Street address

Daneshghah Street- Tabriz university- red building

City

Tabriz

Postal code

Approval date

2010-11-27, 1389/09/06

Ethics committee reference number

8938

Health conditions studied

1

Description of health condition studied

Thoracotomy

ICD-10 code

C34

ICD-10 code description

Malignant neoplasm of bronchus and lung

Primary outcomes

1

Description

pain

Timepoint

2-6-12-24-48 hour

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

total analgesic dose

Timepoint

2-6-12-24-48 hour

Method of measurement

adding together all analgesics recieved

Intervention groups

1

Description

Epidural catheter implacement

Category

Treatment - Surgery

2

Description

Subplural catheter implacement

Category

Treatment - Surgery

3

Description

Intraplural catheter implacment

Category

Treatment - Surgery

4

Description

Inscinal catheter implacment

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dawood Aghamohammadi

Street address

Daneshghah street Imam Reza Hospital- operation room- anesthesia Dept

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz 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

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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Position

Assistant Professor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty