

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of interpleural versus intravenous morphine for pain relief after video-assisted thoracoscopic Surgery

Protocol summary

Summary

The purpose of this randomized double blind clinical trial is to compare the effect of interpleural morphine analgesia with traditional intravenous morphine administration on pain and supplemental analgesic usage after VATS. Forty American Society of Anesthesiologists class I and II scheduled for VATS are randomly assigned to two equal groups for postoperative pain management. At the completion of operation, a catheter was placed in the pleural space under direct vision. At the end of VATS, eligible patients in intervention group will receive a single bolus of 0.1 mg/kg of morphine interpleurally. The patients in the control group will receive a single bolus of 0.1 mg/kg of morphine, intravenously. During the first postoperative 8 hours, pain score at the rest and on coughing, supplemental analgesic requirements, mean arterial pressure, heart rate, SPO2, degree of sedation, and side effects will be monitored every hour.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107046942N1**
Registration date: **2011-07-21, 1390/04/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-21, 1390/04/30

Registrant information

Name

Shideh Dabir

Name of organization / entity

NRITLD, Masih Daneshvari Hospital, Shahid Beheshti

University of Medical Sciences.

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Recruitment status

Recruitment complete

Funding source

National Research Institute of Tuberculosis & Lung diseases

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-10-22, 1390/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of interpleural versus intravenous morphine for pain relief after video-assisted thoracoscopic Surgery

Public title

The effect of interpleural and intravenous morphine on pain after video-assisted thoracoscopic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA Class 1& 2, Age more than or equal 18, Weight more than or equal 40 kg, no limitations in terms of sex, height, surgery duration, type of surgical procedure, number and location of chest tubes. Exclusion criteria: Opium/alcohol addiction, drug abuse, mental retardation, psychological disorders, severe pleural adhesions and fibrosis, bronchopleural

fistula, severe empyema, ASA class more than or equal 3, opioid consumption prior to surgery, inability to clamp chest tubes after surgery

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Research Institute of Tuberculosis & Lung Disease

Street address

Masih Daneshvari Hospital, Darabad, Niavaran

City

Tehran

Postal code

1955841452

Approval date

2004-11-20, 1383/08/30

Ethics committee reference number

p/25/29/5236

Health conditions studied

1

Description of health condition studied

Two different analgesic methods after VATS

ICD-10 code

Y90, Y91,

ICD-10 code description

Supplementary factors related to causes of morbidity and mortality classified elsewhere

Primary outcomes

1

Description

Pain severity after VATS

Timepoint

every one hour during the first postoperative 8 hours

Method of measurement

Visual analogue scale, supplemental analgesic consumption

Secondary outcomes

1

Description

mean arterial pressure

Timepoint

every one hour during first postoperative 8 hours

Method of measurement

NIBP

2

Description

heart rate

Timepoint

every one hour during first postoperative 8 hours

Method of measurement

ECG

3

Description

SPO2

Timepoint

every one hour during first postoperative 8 hours

Method of measurement

pulse oxymeter

4

Description

side effects (nausea, vomiting, pruritus, respiratory depression)

Timepoint

every one hour during first postoperative 8 hours

Method of measurement

observation and question

5

Description

sedation score

Timepoint

every one hour during first postoperative 8 hours

Method of measurement

Ramsay sedation scale

Intervention groups

1

Description

At the end of VATS, eligible patients in control group will receive a single bolus of 0.1 mg/kg of morphine intravenously

Category

Treatment - Drugs

2

Description

At the end of VATS, eligible patients in intervention group will receive a single bolus of 0.1 mg/kg of morphine interpleurally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

National Research Institute of Tuberculosis & Lung Disease

Full name of responsible person

Dr. Shideh Dabir, Associate Professor of Anesthesia

Street address

Department of Anesthesiology, Dr. Masih Daneshvari Hospital, Darabad, Niavaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Research Institute of Tuberculosis & Lung Disease

Full name of responsible person

Dr. Roya Farzanegan

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Tracheal Disease Research Center, masih daneshvari Hospital, Darabad, Niavaran

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Grant name

C-82-621

Grant code / Reference number

C-82-621

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

Yes

Title of funding source

National Research Institute of Tuberculosis & Lung Disease

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

National Research Institute of Tuberculosis & Lung Disease

Full name of responsible person

Dr. Tahereh Parsa

Position

Associate Professor of Anesthesia, Research Deputy

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Associate Professor of Anesthesia, Educational Deputy

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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