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

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Shideh Dabir
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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 analoge scale, supplemental analgesic consumption

Secondary outcomes

1

Description
mean arterial pressure

Timepoint
every one hour during first postoperatve 8 hours

Method of measurement
NIBP

2

Description
heart rate

Timepoint
every one hour during first postoperatve 8 hours

Method of measurement
ECG

3

Description
SPO2

Timepoint
every one hour during first postoperatve 8 hours

Method of measurement
pulse oxymeter

4

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

Timepoint
every one hour during first postoperatve 8 hours

Method of measurement
observation and question

5

Description
sedation score

Timepoint
every one hour during first postoperatve 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
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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
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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