

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of general anesthesia and thoracic epidural anesthesia in diagnostic thoracoscopic operations

Protocol summary

Summary

Patients who need diagnostic thoracoscopy and can lie down in the lateral position in conscious status, will be randomized between two groups. The control group will be undergone the operation by general anesthesia and insertion of double lumen tracheal tube and the intervention group undergone the same operation by epidural anesthesia. After the operation the epidural catheter will be maintained for postoperative analgesia. These variables will be compared between the two groups: duration of operation, heart rate, minimum arterial oxygen saturation, pCO₂ (minimum, maximum), respiratory rate (minimum, maximum), systolic and diastolic blood pressure (minimum, maximum), total hospital stay, total intensive care unit stay, need for mechanical ventilation after the operation, in hospital mortality. Our hypothesis is that there is no difference between the epidural and general anesthesia according to these variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050116473N2**

Registration date: **2014-05-18, 1393/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-18, 1393/02/28

Registrant information

Name

Farzad Kakaei

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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+98 41 1334 1317

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of general anesthesia and thoracic epidural anesthesia in diagnostic thoracoscopic operations

Public title

Comparison of general anesthesia and thoracic epidural anesthesia in diagnostic thoracoscopic operations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: candidate for thoracospy; ASA class I or II; 20-60 Y/O; ability to be in lateral position; little tracheal secretions; no need for preoperative mechanical ventilation Exclusion criteria: no consent for epidural anaesthesia; no cooperation for epidural anaesthesia; inability to perform epidural anaesthesia

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: 30

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tabriz University of Medical Sciences

Street address

Golgasht

City

Tabriz

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

92117

Health conditions studied

1

Description of health condition studied

Pleural effusion, not elsewhere classified

ICD-10 code

J90

ICD-10 code description

Pleurisy with effusion

2

Description of health condition studied

Pleural effusion in conditions classified elsewhere

ICD-10 code

J91

ICD-10 code description

Pleural effusion in conditions classified elsewhere

3

Description of health condition studied

Pneumothorax

ICD-10 code

J93

ICD-10 code description

Pneumothorax

4

Description of health condition studied

Other pleural conditions

ICD-10 code

J94

ICD-10 code description

Other pleural conditions

5

Description of health condition studied

Acute pulmonary insufficiency following thoracic surgery

ICD-10 code

J95.1

ICD-10 code description

Acute pulmonary insufficiency following thoracic surgery

Primary outcomes

1

Description

duration of operation

Timepoint

during the operation of each patient

Method of measurement

with a timer

2

Description

minimum and maximum heart rate

Timepoint

during the operation of each patient

Method of measurement

with an electrocardiograph

3

Description

minimum arterial oxygen saturation

Timepoint

during the operation of each patient

Method of measurement

with a digital pulse oxymeter

4

Description

minimum and maximum arterial pCO2

Timepoint

every half hour during the operation

Method of measurement

with arterial blood gas sampling

5

Description

minimum and maximum respiratory rate

Timepoint

during the operation of each patient

Method of measurement

with a respiratory rate monitor

6

Description

minimum and maximum systolic and diastolic blood pressure

Timepoint

during the operation of each patient

Method of measurement

by NIBP monitor

7

Description

duration of hospital stay

Timepoint

after the operation till discharge

Method of measurement

total hospital stay

8

Description

duration of ICU stay

Timepoint

after the operation till transfer to the ward

Method of measurement

total ICU stay

9

Description

duration of mechanical ventilation

Timepoint

after the operation till extubation

Method of measurement

total hours of need for mechanical ventilation

10

Description

in hospital mortality

Timepoint

after the operation till discharge

Method of measurement

report of death by the attending physician

Secondary outcomes

1

Description

need for conversion to general anesthesia

Timepoint

during the operation

Method of measurement

report of the conversion by the anesthesiologist

2

Description

pain after the operation

Timepoint

6 and 24 hours after the operation

Method of measurement

by visual analog scale

Intervention groups

1

Description

Standard general anesthesia with double lumen tracheal tube insertion in the control group

Category

Treatment - Other

2

Description

Epidural anesthesia by insertion of thoracic epidural catheter and injection of Marcaine in the intervention group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Imam Reza hospital

Full name of responsible person

Ahmad Shaikloo

Street address

Thoracic surgery ward, Imam Reza hospital, Golgasht street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza rashidi

Street address

Golgasht

City

Tabriz

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
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

Full name of responsible person
Samad Beheshti Rouy

Position
Assistant professor of thoracic surgery

Other areas of specialty/work

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Other areas of specialty/work

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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