

# 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, pCO<sub>2</sub> (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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1334 1317

##### Email address

fkakaei@tbzmed.ac.ir

##### 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 thoracoscopy; 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

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## Person responsible for scientific inquiries

### Contact

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Davood Aghamohammadi

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## Person responsible for updating data

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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*