

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison of respiratory capacity and short term complications between single port versus standard diagnostic Video-assisted Thoracoscopy for patients with lung lesions needed to diagnosis

#### Protocol summary

##### Study aim

comparison of clinical outcomes between single port and standard diagnostic thoracoscopy

##### Design

40 patients with lung lesions needed to diagnosis are allocated at non blinded clinical trial. These patients are randomly allocated into two intervention (single port thoracoscopy) and control (standard thoracoscopy) groups using a balanced block randomization technique.

##### Settings and conduct

Referral patients to surgical clinic with lung lesions and with an indication for thoracoscopy will be entered into study according to the eligibility criteria and after giving an informed consent. Patients are randomly allocated into two intervention (single port thoracoscopy) and control (standard thoracoscopy) groups using a balanced block randomization technique. After diagnostic procedure vital capacity, post operative pain, complications and stay in hospital are compared between two groups. This study is done at Modarres hospital from Shahid Beheshti University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with lung disease needed to diagnostic thoracoscopy  
Exclusion criteria: previous thoracotomy and any condition that prohibits thoracoscopy

##### Intervention groups

Diagnostic single port thoracoscopy for patients with lung lesion (intervention group); Diagnostic standard three ports thoracoscopy for patients with lung lesion (control group)

##### Main outcome variables

Respiratory capacities; pain after surgery; complications after surgery; hospital stay duration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160803029181N5**

Registration date: **2018-03-06, 1396/12/15**

Registration timing: **retrospective**

Last update: **2018-03-06, 1396/12/15**

Update count: **0**

##### Registration date

2018-03-06, 1396/12/15

##### Registrant information

##### Name

Nasser Malekpour Alamdari

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2207 4089

##### Email address

nassermalekpour@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

2017-09-21, 1396/06/30

##### Actual recruitment end date

2018-01-21, 1396/11/01

##### Trial completion date

empty

### Scientific title

Comparison of respiratory capacity and short term complications between single port versus standard diagnostic Video-assisted Thoracoscopy for patients with lung lesions needed to diagnosis

### Public title

Survey of clinical outcomes in single port diagnostic thoracoscopy

### Purpose

Diagnostic

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Lung disease needs to diagnostic thoracoscopy

#### Exclusion criteria:

Previous thorotomy Complete collapse Impossibility in intervened sided Controlateral severe lung disease Controlateral airway lesion

### Age

No age limit

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **28**

Actual sample size reached: **27**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Patients were randomly enrolled in two groups single port diagnostic thoracoscopy(intervention) and three ports diagnostic thoracoscopy with randomized block technique

### 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

Ethical committee of Shahid Beheshti University of Medical Sciences

##### Street address

Velenjak; Daneshju Ave; Shahid Beheshti University of Medical Sciences

### City

Tehran

### Province

Tehran

### Postal code

1985717443

### Approval date

2017-07-28, 1396/05/06

### Ethics committee reference number

IR.SBMU.RETECH.REC.1396.331

## Health conditions studied

### 1

#### Description of health condition studied

Single incision diagnostic thoracoscopy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Respiratory capacities

#### Timepoint

Admission,discharge,2 weeks later

#### Method of measurement

Spiropmetry

### 2

#### Description

Pain after surgery

#### Timepoint

Discharge,2 weeks later

#### Method of measurement

Visual analogue scale

### 3

#### Description

Complications after surgery

#### Timepoint

Discharge,2 weeks later

#### Method of measurement

Check list

### 4

#### Description

Hospital stay

#### Timepoint

Admission,discharge

#### Method of measurement

Check list

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients who have an indication for thoracoscopy will receive a single port that is entered into pleural space with a 2.5 cm incision at 5th intercostal space on midaxillary line, and a biopsy will be taken

#### Category

Diagnosis

### 2

#### Description

Control group: Patients who have an indication for thoracoscopy will receive the standard procedure with 3 ports. One 11 mm port at 7th intercostal space on midaxillary line for thoracoscope, and two more 5 mm ports at 4th and 7th intercostal space on posterior axillary line are entered into pleural space and a biopsy will be taken.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Modarres hospital

##### Full name of responsible person

Nasser Malekpour

##### Street address

Modarres Hospital;Kaj Sq;Saadat abad;

##### City

Tehran

##### Province

Tehran

##### Postal code

1998734383

##### Phone

+98 21 2206 9355

##### Email

nassermalekpour@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

Shahid Beheshti University of Medical Sciences;Daneshju Ave;Velenjak

##### City

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1985717443

#### Phone

+98 21 23871

#### Email

nassermalekpour@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Nasser Malekpour

##### Position

Assistant professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

General Surgery

##### Street address

Modarres hospital;Kaj sq;Saadat abad

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Tehran

##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Nasser Malekpour

##### Position

Assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Nasser Malekpour  
**Position**  
Assistant professor  
**Latest degree**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no further data

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available