

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;

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Tehran

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1998734383

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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

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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

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Person responsible for scientific inquiries

Contact

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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
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Position
Assistant professor
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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