

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Thoracotomy and Video Assisted Thoracoscopic Surgery in the treatment of Grade II pleural Empyema

Protocol summary

Study aim

The comparison of Thoracotomy with Video-Assisted Thoracoscopic Surgery in treatment of grade II pleural empyema

Design

A non-randomized clinical trial with a parallel control group designed and enrolled in 42 patients.

Settings and conduct

The procedures were done in the operation room of Ayatollah Roohani Hospital in Babol city.

Participants/Inclusion and exclusion criteria

Patients who were admitted with grade II empyema according to chest X-ray and pleural tap, despite the chest tube insertion, drainage, and pulmonary expansion have not been established were included in the trial. Also, the interval between the onset of symptoms and intervention was up to 6 weeks. patient with an unstable clinical condition, below 15 years old, immunocompromised state, positive pleural cytology for malignancy were excluded from the study.

Intervention groups

Patients in the intervention group were undergone Video-Assisted Thoracoscopic Surgery. Patients in the control group were undergone thoracotomy.

Main outcome variables

Complete lung expansion rate, Post-operation duration of hospitalization, Operation duration time, Post-operation pain level, Convert rate to thoracotomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042594N1**

Registration date: **2019-05-07, 1398/02/17**

Registration timing: **retrospective**

Last update: **2019-05-07, 1398/02/17**

Update count: **0**

Registration date

2019-05-07, 1398/02/17

Registrant information

Name

morteza yaghini

Name of organization / entity

Country

Iran (Islamic Republic of)

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drmortezayaqini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2017-10-23, 1396/08/01

Actual recruitment end date

2019-02-19, 1397/11/30

Trial completion date

2019-02-19, 1397/11/30

Scientific title

Comparison of Thoracotomy and Video Assisted Thoracoscopic Surgery in the treatment of Grade II pleural Empyema

Public title

Comparison of Thoracotomy and Video Assisted Thoracoscopic Surgery in the treatment of Grade II pleural Empyema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have complained of pleural effusion and after radiography and confirmation, have been diagnosed with Tap and have been classified as grade 2 empyema, which despite the introduction of the chest tube, drainage and pulmonary distension have not completely occurred. The interval between the onset of symptoms and the procedure is up to 6 weeks

Exclusion criteria:

Patients with immune deficiency and consumption of immunosuppressive drugs Unstable patients age below 15 years old positive cytology of plural fluid for malignancy

Age

From **15 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to one of the two treatment groups based on the admission date serially.

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

Ethics committee of Babol University of Medical Sciences

Street address

GanjAfrooz street, Babol university of medical sciences

City

Babol

Province

Mazandaran

Postal code

47745-47176

Approval date

2018-11-18, 1397/08/27

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.185

Health conditions studied

1

Description of health condition studied

Empyema

ICD-10 code

J86

ICD-10 code description

Pyothorax

Primary outcomes

1

Description

Complete lung expansion rate

Timepoint

During 24 h after surgery

Method of measurement

According to chest X-ray

Secondary outcomes

1

Description

Post-operation duration of hospitalization

Timepoint

After discharge from hospital

Method of measurement

Post-operation hospitalization day/days

2

Description

Operation duration time

Timepoint

Just after surgery

Method of measurement

The difference between the start and end time of the surgery

3

Description

Post-operation pain level

Timepoint

Every day after surgery until discharge, once a day

Method of measurement

according to Visual Analogue Scale

Intervention groups

1

Description

Intervention group: Video-assisted thoracoscopic surgery

Category

Treatment - Surgery

2**Description**

Control group: posterolateral thoracotomy surgery

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Rouhani Hospital (Babol)

Full name of responsible person

Ramin Nosrati

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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

No

Title of funding source

Vice-chancellor for research, school of medicine, Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Morteza Yaqini

Position

Surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, all clinical and demographic data are encoded in SPSS software for sharing.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Doctors and people working in academic institutions related to medical sciences

Under which criteria data/document could be used

Use of this research data will be permitted in meta-analysis studies

From where data/document is obtainable

Contact: drmortezayaqini@gmail.com, to receive the data

What processes are involved for a request to access data/document

The applicant will be contacted within 48 hours, and if the academic and employment records of the research environment are properly submitted, research data will be provided to the applicant upon confirmation of the identity of the originator.

Comments