

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Diagnostic yield and Complications of Transbronchial Lung Biopsy with Fluoroscopic Guidance: A Randomized Clinical Trial

Protocol summary

Study aim

The aim of this study is to evaluate the results and complications of transbronchial lung biopsy with fluoroscopic guidance.

Design

two arm parallel group randomized without blinded procedure

Settings and conduct

this study will conduct among patients referred to bronchoscopy ward of Afzalipour Hospital that is a referral and university medical center in Kerman.

Participants/Inclusion and exclusion criteria

This randomized clinical trial will conduct on patients with pulmonary parenchymal lesions. all patients will be included the study unless patients with severe hypoxemia, severe asthma, hemodynamic instability, malignant arrhythmia and severe hemoptysis, who will be excluded.

Intervention groups

In control and subject groups ransbronchial lung biopsy were performed using fiberoptic bronchoscopy without fluoroscopic guidance and with fluoroscopic guidance respectively.

Main outcome variables

The pneumothorax rate, bleeding during transbronchial lung biopsy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150606022566N3**

Registration date: **2018-10-30, 1397/08/08**

Registration timing: **retrospective**

Last update: **2018-10-30, 1397/08/08**

Update count: **0**

Registration date

2018-10-30, 1397/08/08

Registrant information

Name

Seyed Mehdi Hashemi Bajgani

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Diagnostic yield and Complications of Transbronchial Lung Biopsy with Fluoroscopic Guidance: A Randomized Clinical Trial

Public title

Transbronchial Lung Biopsy with Fluoroscopic Guidance

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

patients with pulmonary parenchymal lesions

Exclusion criteria:
 patients with pulmonary parenchymal lesions with severe hypoxemia patients with pulmonary parenchymal lesions with severe refractory asthma patients with pulmonary parenchymal lesions with hemodynamic instability patients with pulmonary parenchymal lesions with malignant arrhythmia patients with pulmonary parenchymal lesions with severe hemoptysis

Age
 No age limit

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **150**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Patients will be classified into two groups using random number table. units of randomization is individuals.

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 Kerman University of Medical Sciences

Street address

Afzalipour Hospital ,Imam Khomeini Highway,

City

Kerman

Province

Kerman

Postal code

7616914111

Approval date

2015-01-05, 1393/10/15

Ethics committee reference number

IR.KMU.REC.1393.340

Health conditions studied

1

Description of health condition studied

Parenchymal lung disease

ICD-10 code

J40, J41

ICD-10 code description

chronic lower respiratory diseases

Primary outcomes

1

Description

overall diagnosis of lesions

Timepoint

during bronchoscopy

Method of measurement

fiberoptic bronchoscop

2

Description

Pneumothorax rate

Timepoint

After Bronchoscopy

Method of measurement

Chest X-Ray

3

Description

Bleeding rate

Timepoint

After Bronchoscopy

Method of measurement

Chest X-Ray

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Transbronchial lung biopsy will perform using fiberoptic bronchoscopy under fluoroscopic-guidance

Category

Diagnosis

2

Description

Control group: Transbronchial lung biopsy will performed in control group using fiberoptic bronchoscopy without fluoroscopic-guidance

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Dr. Seyedmehdi Hashemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhty

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Jahad Blv.Vice chancellor for research,Kerman
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drpardakhty@yahoo.com

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

Yes

Title of funding source

Kermanshah 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

Kerman University of Medical Sciences

Full name of responsible person

Dr. Seyed Mehdi hashemi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
Yes - There is 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
Title and more details about the data/document
all collected data are not shareable.
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
only available for people working in academic institutions
Under which criteria data/document could be used
all collected data are not shareable.
From where data/document is obtainable
all collected data are not shareable.
What processes are involved for a request to access data/document
all collected data are not shareable.
Comments
all collected data are not shareable.