Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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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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
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Person responsible for updating data

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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.