

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Hemodynamic Changes in Patients undergoing Diagnostic Bronchoscopy using Remifentanyl\_ Propofol versus Remifentanyl\_ Ketamine

#### Protocol summary

##### Study aim

Hemodynamic changes in Patients undergoing Diagnostic Bronchoscopy using Remifentanyl\_ Propofol versus Remifentanyl\_ Ketamine

##### Design

In this search, 78 eligible Pulmonary Patients were Chosen purposefully for Diagnostic Bronchoscopy and a code was allocated to each one of them. Then, patients were randomly divided into two intervention groups.

##### Settings and conduct

This study will be done at General Operation Room of Imam Khomeini hospital in Ardabil\_ Iran. Type of study is Double blinde, That Kinde of sedative Drugs will be hidden from Both of bronchoscopist and Patient.

##### Participants/Inclusion and exclusion criteria

18 to 65 Y/O Patients with Pulmonary diseases (ASA 1\_3) chosen for Diagnostic Bronchoscopy , without Uncontrolled Cardiovascular or carebral Diseases

##### Intervention groups

After Cardiopulmonary monitoring, One of the groups will be sedated by Remifentanyl (0.1 microgram/kg/min) plus Propofol (0.5 mg/kg) and other groups by Remifentanyl (0.1 microgram/kg/min) plus Ketamine (0.25 mg/kg) ].

##### Main outcome variables

Hemodynamic changes ( HR, SBP, DBP, MAP, Spo2) while Bronchoscopy and Consciousness state, Bronchoscopist & Patients consent at the End of Procedure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171202037716N1**

Registration date: **2017-12-13, 1396/09/22**

Registration timing: **prospective**

Last update: **2017-12-13, 1396/09/22**

Update count: **0**

##### Registration date

2017-12-13, 1396/09/22

##### Registrant information

###### Name

Davood Seifi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3352 1355

###### Email address

da.seifi@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-05, 1396/10/15

##### Expected recruitment end date

2018-09-06, 1397/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Hemodynamic Changes in Patients undergoing Diagnostic Bronchoscopy using Remifentanyl\_ Propofol versus Remifentanyl\_ Ketamine

##### Public title

Remifentanyl\_ Propofol versus Remifentanyl\_ Ketamine in Diagnostic Bronchoscopy

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

18 to 65 y/o Patients with Pulmonary Diseases ( ASA : 1\_3 ) that selected by Pulmonologist for Diagnostic Bronchoscopy  
**Exclusion criteria:**  
Patients with Opioid addiction Untreated HTN or IHD Loss of Consciousness Epileptic Patients

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **76**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, Random allocation rule will be used , 76 Similar Closed packages will be performed: 38 Packages contain Blue Card ( Remifentanil\_ propofol Group) and 38 Packages contain Green Card ( Remifentanil\_ Ketamine Group), then Packages will be picked up and opened randomly without replacing and created sequence will be recorded.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Bronchoscopist and Patients will not be aware from the type of administrated drugs

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ardabil University of Medical Sciences

**Street address**

Daneshgah Ave.

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5618985991

**Approval date**

2017-10-30, 1396/08/08

**Ethics committee reference number**

IR.ARUMS.REC.1396.137

**Health conditions studied**

**1**

**Description of health condition studied**

Sedation for Diagnostic Bronchoscopy

**ICD-10 code**

R91

**ICD-10 code description**

Abnormal findings on diagnostic imaging of lung

**Primary outcomes**

**1**

**Description**

Percent of Systolic Blood Pressure Rising after Drugs administration

**Timepoint**

Record of Systolic Blood Pressure Before, During and After Procedure

**Method of measurement**

Non invasive Manometer

**Secondary outcomes**

**1**

**Description**

Consciousness State of Patients

**Timepoint**

10 minutes after end of Procedure

**Method of measurement**

Ramsey Sedation Score

**Intervention groups**

**1**

**Description**

Intervention group: Remifentanil 0.1 microgram/kg/min Intra venously 3 min Before Procedure plus Propofol 0.5 mg/kg Intra venously

**Category**

Treatment - Other

**2**

**Description**

Intervention group: Remifentanil 0.1 microgram/kg/min Intra venously 3 min Before Procedure plus Ketamine 0.25 mg/kg Intra venously

**Category**

Treatment - Other

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

Doctor Hassan Gobadi

**Street address**

Ataee Ave.

**City**

Ardabil

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**Postal code**

5618985991

**Email**

Emamhe@arums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Doctor Akhavan Akbari

**Street address**

Danashgah Ave.

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**Postal code**

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**Email**

info@arums.ac.ir

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

Yes

**Title of funding source**

Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Davood Seifi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

No. 27, Resalat 3 Ave. 13 Aban Ave.

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**Postal code**

5619814386

**Phone**

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**Email**

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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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**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**

Not applicable

**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