# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparative study of fibroptic bronchoscopic with two method: midazolam base versus lidocaine base in patients refered at lung clinic in AJA 501 hospital

## Protocol summary

**Study aim**

Comparative study of fibroptic bronchoscopic with two method: midazolam base versus lidocaine base in patients refered at lung clinic in Imam Reza Hospital 1396-1397

**Design**

A clinical trial with parallel, double-blind, randomized, black-and-white groups on 140 patients in 2 groups.

**Settings and conduct**

Lung Clinic of Imam Reza Hospital. In this study, neither the patient nor the collector knew how the samples were distributed. The obtained information is then statistically analyzed by the person in charge of statistical work who does not know how the patients are distributed.

**Participants/Inclusion and exclusion criteria**

Participants: All male and female patients aged 18 to 80 years and ASA I-II. Exclusion criteria: include people with a history of sore throat and lung disease with 290% o2sat (hypoxemia) - people with EF˂40% - people with HR˂50 - people with hypotension BP˂90 mmHg -Pregnant or lactating women - People with a long history of taking antipsychotic or sedative drugs.

**Intervention groups**

Intervention groups: In one group, 3 mg equivalent to 3 ml of midazolam is administered intravenously in a syringe whose volume has been increased to 5 cc by adding 2 cc of distilled water, and in the basal lidocaine group instead of a syringe containing midazolam Containing 5 cc of lidocaine (lidocaine 2%) is used intravenously

**Main outcome variables**

Type of basic anesthetic (including midazolam and lidocaine)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20110103005536N8**
Registration date: **2020-09-11, 1399/06/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-11, 1399/06/21**
Update count: **0**

**Registration date**

2020-09-11, 1399/06/21

**Registrant information**

**Name**

Mohamadreza Rafiei

**Name of organization / entity**

Artesh University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8802 8933

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-05-22, 1398/03/01

**Expected recruitment end date**

2021-03-19, 1399/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of fibroptic bronchoscopic with two method: midazolam base versus lidocaine base in patients refered at lung clinic in AJA 501 hospital

**Public title**
Comparative study of fibroptic bronchoscopic with two method: midazolam base versus lidocaine base
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
male and female patients aged 18 to 80 years ASA I-II
**Exclusion criteria:**
People with a history of sore throat and lung disease with 90% o2sat (hypoxemia) People with Ejection fraction less than 40% people with hearth rate less than 50 people with hypotension less than 90 mmHg People with III and grade II conduction blocks People with liver failure (2-fold increase in liver enzymes) and kidney failure (creatinine more than 2 mg / dL) Pregnant or lactating women People With a history of long-term use of antipsychotic drugs or sedatives.
**Age**
From **18 years** old to **80 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **140**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients are randomly assigned between the two groups (70 people in each group) by Simple Random Sampling method using black and white cards, so that patients with black card to group one, and patients with white card to Group two is assigned and this process is repeated again.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this study, neither the patient nor the collector knew how the samples were distributed. The obtained information is then statistically analyzed by the person in charge of statistical work who does not know how the patients are distributed.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of aja univercity of medical sciences
**Street address**
Etemadzadeh St., West Fatemi Ave.
**City**
Tehran
**Province**
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**Postal code**
8158177365
**Approval date**
2019-04-28, 1398/02/08
**Ethics committee reference number**
IR.AJAUMS.REC.1398.022

## Health conditions studied

**1**

**Description of health condition studied**
bronchoscopy
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Type of basic anesthetic
**Timepoint**
Before the intervention
**Method of measurement**
Based on the name of the drug

## Secondary outcomes

**1**

**Description**
Complications of bronchoscopy
**Timepoint**
During the intervention
**Method of measurement**
Based on the need for intubation, nausea, decreased oxygen saturation, sore throat, cough

**2**

**Description**
Duration of bronchoscopy
**Timepoint**
During the intervention
**Method of measurement**
Based on time from start to end of the procedure

**3**

**Description**

Physician satisfaction
**Timepoint**
After the intervention
**Method of measurement**
Based on the doctor's satisfaction with the procedure from 1 to 5 based on likret scale

**4**

**Description**
Patient satisfaction
**Timepoint**
After the intervention
**Method of measurement**
Based on the patient's satisfaction with the procedure from 1 to 5 based on likret scale

## Intervention groups

**1**

**Description**
Intervention group: In one group, for performing fibropeptic bronchoscopy, the method of anesthesia is used based on "midazolam". It is administered intravenously and after the fibroptic bronchoscope enters the patient's mouth and before passing through the vocal cords with a syringe with a volume of 5 cc of distilled water is poured on the vocal cords (through the place of fluid entry in the bronchoscope) and then After passing the bronchoscope through the vocal cords, a syringe with a volume of 5 cc of distilled water is poured into the patient's trachea (tracheobronchial tree).
**Category**
Treatment - Other

**2**

**Description**
Intervention group: In one group, for performing fibropeptic bronchoscopy, the method of anesthesia based on "lidocaine" is used. A syringe containing 5 cc of lidocaine (2% lidocaine) is used intravenously and after entering the fibroptic bronchoscope. Patient and before passing the vocal cords with a syringe with a volume of 5 cc lidocaine 2% is poured on the vocal cords (through the place of fluid entry in the bronchoscope) and after passing the bronchoscope through the vocal cords with a syringe With a volume of 5 cc of 2% lidocaine is poured into the patient's trachea (tracheobronchial tree).
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
501 AJA Hospital
**Full name of responsible person**
Dr. Mohammadreza Rafiei
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Artesh University of Medical Sciences
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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**
Artesh 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**
Artesh University of Medical Sciences
**Full name of responsible person**
Dr. Mohammadreza Rafiei
**Position**
Associate professor

**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
Not applicable
**Title and more details about the data/document**
All data can be shared after it is unrecognizable
**When the data will become available and for how long**
Start the access period after printing the results
**To whom data/document is available**
All researchers and colleagues in this field
**Under which criteria data/document could be used**
For therapeutic-research purposes and by mentioning the names of the authors of the article
**From where data/document is obtainable**
Dr. mohammadreza rafiei
**What processes are involved for a request to access data/document**
Sending an Email to Dr. mohammadreza rafiei and receive data and documentation if needed in the shortest time
**Comments**