

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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)

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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.

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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

Street address

Etemadzadeh St., West Fatemi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Saeed Soleyman Meygooni

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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