Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparing the effects of Propofol-Ketamine with Propofol-Remifentanile on blood pressure and heart rate changes in patients candidate for Fibro optic Bronchoscopy

Protocol summary

Study aim

The comparison effect of prescribing Propofol-Remifentanil with Propofol-Ketamine on blood pressure and heart rate changes in patients undergoing fibropeptic bronchoscopy

Design

In this double blind randomized clinical trial study with paralel groups, 68 patients candidate for Fibrooptic Bronchoscopy are selected and randomly allocated in to two groups of 38 subjects by Random Alocation software. The first group receive the combination of Ketamine + Remifentanil and the second group receive Propofol + Remifentanil and the incidence of Hemodynamic disorders and other complications during the procedure and in recovery will be determined and will be compared between two groups.

Settings and conduct

This double-blind clinical trial study will done in 2019 at Alzahra Hospital in Isfahan on patients candidates for fibro-optics bronchoscopy . In this study, patients and researchers are not aware of the type of drug they receive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate for Bronchoscopy; age range between 18-60 years; Patient agrees to participate. Non-inclusion criteria: History of alcohol and drug addiction; History of chronic illness such as mental disorders; History of seizure .

Intervention groups

Intervention group 1: Propofol-Remifentanil. Receiving 1µg / kg Remifentanil + 10 mg of propofol and 50 ug/kg per minute as the maintenance dose. Intervention group 2: Propofol-Ketamine, Receiving 0.5 mg / kg of ketamine+ 10 mg of propofol and 50 ug/kg per minute as the maintenance dose.

Main outcome variables

blood pressure; heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N33**
Registration date: **2019-08-17, 1398/05/26**
Registration timing: **prospective**

Last update: **2019-08-17, 1398/05/26**
Update count: **0**

Registration date

2019-08-17, 1398/05/26

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effects of Propofol-Ketamine with Propofol-Remifentanile on blood pressure and heart rate changes in patients candidate for Fibro optic Bronchoscopy

Public title
Comparison effect of three different drug combinations on Blood Pressure and Heart rate of patients under Bronchoscopy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
ASA (American Society of Anesthesiologists) < 4 patients candidate for bronchoscopy

Exclusion criteria:
body mass index>35 history of alcohol consumption or addiction history of severe allergy history of psychologic diseases history of epilepsy of seizure patient with unstable status

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 86 patients candidate for bronchoscopy were selected and divided into two groups of 38 subjects by Random Allocation software .

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind clinical trial. Patients and the investigator are not aware about the type of drug injected. The medications are prepared by one of the operating room personnel in the same and encoded syringes and will be given to researcher for injection.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Department of anesthesiology, Alzahra hospital, Soffeh street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2017-01-31, 1395/11/12

Ethics committee reference number
IR.MUI.REC.1395.3.695

Health conditions studied

1

Description of health condition studied
Bronchoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Blood Pressure

Timepoint
every 5 minutes during procedure and recovery

Method of measurement
palsoxymetery

Secondary outcomes

1

Description
heart rate

Timepoint
every 5 minutes during procedure and recovery

Method of measurement
palsoxymetery

Intervention groups

1

Description
Intervention group: receive 1ug/kg injectable Remifentanil (Razavi Pharmacational institute) with 0.5 mg/kg ketamin(made by Bremore Company) through intravenous infusion.

Category
Prevention

2

Description
Control group: receive combination of remifentanyl + propoful
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Esfahan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The data belongs to the government agency.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Because the study data is related to the government organization, there is no way to share it

When the data will become available and for how long
any time

To whom data/document is available
any person

Under which criteria data/document could be used
Under no circumstances

From where data/document is obtainable
any person

What processes are involved for a request to access data/document
any procedure

Comments