

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparing the effects of Propofol-Ketamine with Propofol-Remifentanil on blood pressure and heart rate changes in patients candidate for Fiberoptic 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 fiberoptic bronchoscopy

Design

In this double blind randomized clinical trial study with parallel groups, 68 patients candidate for Fiberoptic Bronchoscopy are selected and randomly allocated in to two groups of 38 subjects by Random Allocation 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 fiberoptics 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

mehrabi@mui.ac.ir

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-Remifentanil 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

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Isfahan

Province

Isfahan

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

palsoxymetry

Secondary outcomes

1

Description

heart rate

Timepoint

every 5 minutes during procedure and recovery

Method of measurement

palsoxymetry

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 + propofol

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Zeynab Mohebbi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ali Mehrabi

Position

Statistical Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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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