# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparison of propofol sedation and lidocaine-propofol combination in patients undergoing bronchoscopy

## Protocol summary

**Study aim**

The aim of this study is to determine if adding lidocaine to propofol is effective in sedating patients undergoing bronchoscopy.

**Design**

Interventional Clinical trial , two parallel groups, triple blinded, randomised study, phase 3 study on 60 patients

**Settings and conduct**

This study will be done on patients undergoing bronchoscopy in al zahra hospital in winter of 1402 and spring of 1403. Patients, researcher and data analyst are blinded

**Participants/Inclusion and exclusion criteria**

Inclusion criteria; 1. Age between 18 and 60 2. American Society of Anesthesiologists(ASA) physical status classification system class I or class II 3. Bronchoscopy candidate both genders Exclusion Criteria: 1. Opioid or analgesic usage 24 hours before procedures 2. History of beta blocker usage 3. Allergy to drugs 4. Patients with severe cardiovascular diseases, asthma, renal disease, hepatic disease, chronic respiratory disease 5. Immunodeficiency 6. Alcohol consumption 24 hours before procedure 7. Muscular weakness

**Intervention groups**

Group 1; propofol group for each patient an stat dose of propofol 1 mg/kg is calculated and then injected. After the initial induction if sedation score 5 is not achieved, propofol infusion with the rate of 70 µg/kg/min will be started. The amount of drug used to achieve and maintain Sedation Score 5 will be calculated. Groip 2; lidocaine-propofol combination for each patient an stat dose of propofol 1mg/kg and lidocaine 1.5 mg/kg is calculated and then injected. After the initial induction if sedation score 5 is not achieved, propofol infusion with the rate of 70 µg/kg/min will be started.The amount of drug used to achieve and maintain Sedation Score 5 will be calculated.

**Main outcome variables**

Blood pressure, Arterial oxygen saturation, Heart rate, Sedation score

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160307026950N57**
Registration date: **2024-01-29, 1402/11/09**
Registration timing: **prospective**

Last update: **2024-01-29, 1402/11/09**
Update count: **0**

**Registration date**

2024-01-29, 1402/11/09

**Registrant information**

**Name**
Behzad Nazemroaya
**Name of organization / entity**
Isfahan University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3212 3543
**Email address**
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-02-04, 1402/11/15

**Expected recruitment end date**

2024-03-15, 1402/12/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Comparison of propofol sedation and lidocaine-propofol combination in patients undergoing bronchoscopy

**Public title**
Comparison of propofol sedation and lidocaine-propofol combination in patients undergoing bronochoscopy

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Minimum 18 years of age and maximum 60 ASA I or ASA II group of patients Bronchoscopy candidate either male or female

**Exclusion criteria:**
Analgesics or Opioid use 24 hours before procedure Previous use of Beta blockers Any known allergy to drugs used in this trial Patients with a past medical history of severe cardiovascular diseases, Asthma, Renal disease, Hepatic disease, chronic respiratory disease Past history of Drug Allergy Immunodeficiency Alcohol consumption 24 hours before procedure Muscular weakness

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

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Method of randomization in this trial will be simple random sampling

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
This will be a triple blinded study. Drugs will be prepared by OR staff in syringes labeled with specific codes and then handed to the researcher. therefore the patient and the researcher won't know the difference. The data will be given to the data analyst who is also blinded.

**Placebo**
Not 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**
Hezar jarib street

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673461

**Approval date**
2024-01-07, 1402/10/17

**Ethics committee reference number**
IR.MUI.MED.REC.1402.369

## Health conditions studied

### 1

**Description of health condition studied**
Anaesthesia

**ICD-10 code**
Y48.4

**ICD-10 code description**
Anaesthetic, unspecified

## Primary outcomes

### 1

**Description**
Heart rate

**Timepoint**
Before induction, 3 minutes after induction, 10 minutes after induction, 20 minutes after induction

**Method of measurement**
پالس اکسیمتری

### 2

**Description**
Blood Pressure

**Timepoint**
Before induction, 3 minutes after induction, 10 minutes after induction, 20 minutes after induction

**Method of measurement**
non invasive manometer

## Secondary outcomes

### 1

**Description**
sedation level

**Timepoint**

Before induction, 3 minutes after induction, 10 minutes after induction, 20 minutes after induction

**Method of measurement**

Sedation Score

## Intervention groups

### 1

**Description**

Propofol; for each patient an stat dose of propofol 1 mg/kg is calculated and then injected. After the initial induction if sedation score 5 is not achieved, propofol infusion with the rate of 70 µg/kg/min will be started. The amount of drug used to achieve and maintain Sedation Score 5 will be calculated.

**Category**

Treatment - Drugs

### 2

**Description**

Propofol-Lidocaine, for each patient an stat dose of propofol 1mg/kg and lidocaine 1.5 mg/kg is calculated and then injected. After the initial induction if sedation score 5 is not achieved, propofol infusion with the rate of 70 µg/kg/min will be started. The amount of drug used to achieve and maintain Sedation Score 5 will be calculated.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Al-Zahra Hospital

**Full name of responsible person**

Behzad Nazemroaya

**Street address**

Anesthesiology Department, Al-Zahra Hospital, Soffeh Blvd

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**Email**

behzad_nazem@med.mui.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Research Vicar

**Street address**

Vice Chancellor for Research, Building4, Isfahan University Of Medical Sciences, Hezarjirib St.

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**Province**

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haghjoo@med.mui.ac.ir

**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**

Behzad Nazemroaya

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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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)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
There is no further information

**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**
No - There is not 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