Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 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
behzad_nazem@med.mui.ac.ir

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

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 5555

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.

City

Isfehan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 5555

Email

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

Department of Anesthesiology, Al Zahra Hospital, Soffeh Blvd, Isfehan

City

Isfehan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 5555

Email

behzad_nazem@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Behzad Nazemroaya

Position
Associate professor

Latest degree
Specialist

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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Behzad Nazemoaya

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Phone
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Email
behzad_nazem@med.mui.ac.ir

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