Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Hemodynamic Changes in Patients undergoing Diagnostic Bronchoscopy using Remifentanil_ Propofol versus Remifentanil_ Ketamine

Protocol summary

Study aim
Hemodynamic changes in Patients undergoing Diagnostic Bronchoscopy using Remifentanil_ Propofol versus Remifentanil_ Ketamine

Design
In this search, 78 eligible Pulmonary Patients were Chosen purposefully for Diagnostic Bronchoscop and a code was allocated to each one of them. Then, patients were randomly divided into two intervention groups.

Settings and conduct
This study will be done at General Operation Room of Imam Khomeini hospital in Ardabil_ Iran. Type of study is Double blinde, That Kinde of sedative Drugs will be hiden from Both of bronchoscopist and Patient.

Participants/Inclusion and exclusion criteria
18 to 65 Y/O Patients with Pulmonary diseases (ASA 1_3) chosen for Diagnostic Bronchoscopy , without Uncontrolled Cardiovascular or carebral Diseases

Intervention groups
After Cardiopulmonary monitoring, One of the groups will be sedated by Remifentanil (0.1 microgram/kg/min) plus Propofol (0.5 mg/kg) and other groups by Remifentanil (0.1 microgram/kg/min) plus Ketamine (0.25 mg/kg)].

Main outcome variables
Hemodynamic changes (HR, SBP, DBP, MAP, Spo2) while Bronchoscopy and Consciousness state, Bronchoscopist & Patients consent at the End of Procedure

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171202037716N1**
Registration date: **2017-12-13, 1396/09/22**
Registration timing: **prospective**

Last update: **2017-12-13, 1396/09/22**
Update count: **0**

Registration date
2017-12-13, 1396/09/22

Registrant information
Name
Davood Seifi
Name of organization / entity
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Iran (Islamic Republic of)
Phone
+98 45 3352 1355
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-05, 1396/10/15
Expected recruitment end date
2018-09-06, 1397/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Hemodynamic Changes in Patients undergoing Diagnostic Bronchoscopy using Remifentanil_ Propofol versus Remifentanil_ Ketamine

Public title
Remifentanil_ Propofol versus Remifentanil_ Ketamine in Diagnostic Bronchoscopy
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:

18 to 65 y/o Patients with Pulmonary Diseases (ASA : 1_3) that selected by Pulmonologist for Diagnostic Bronchoscopy

Exclusion criteria:

Patients with Opioid addiction Untreated HTN or IHD Loss of Consciousness Epileptic Patients

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Random allocation rule will be used , 76 Similar Closed packages will be performed: 38 Packages contain Blue Card (Remifentanil_ propofol Group) and 38 Packages contain Green Card (Remifentanil_ Ketamine Group), then Packages will be picked up and opened randomly without replacing and created sequence will be recorded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Bronchoscopist and Patients will not be aware from the type of administrated drugs

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ḍaneshgah Ave.

City

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Province

Ardabil

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5618985991

Approval date

2017-10-30, 1396/08/08

Ethics committee reference number

IR.ARUMS.REC.1396.137

Health conditions studied

1

Description of health condition studied

Sedation for Diagnostic Bronchoscopy

ICD-10 code

R91

ICD-10 code description

Abnormal findings on diagnostic imaging of lung

Primary outcomes

1

Description

Percent of Systolic Blood Pressure Rising after Drugs administeration

Timepoint

Record of Systolic Blood Pressure Before, During and After Procedure

Method of measurement

Non invasive Manometer

Secondary outcomes

1

Description

Consciousness State of Patients

Timepoint

10 minutes after end of Procedure

Method of measurement

Ramsey Sedation Score

Intervention groups

1

Description

Intervention group: Remifentanil 0.1 microgram/kg/min Intra venously 3 min Before Procedure plus Propofol 0.5 mg/kg Intra venously

Category

Treatment - Other

2

Description

Intervention group: Remifentanil 0.1 microgram/kg/min Intra venously 3 min Before Procedure plus Ketamine 0.25 mg/kg Intra venously

Category

Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Doctor Hassan Gobadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ardabil 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
Ardabil University of Medical Sciences
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Davood Seifi
Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available