Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparison of the sedative effects of diphenhydramine and dexmedetomidine in fiberoptic bronchoscopy of patients

Protocol summary

Study aim
Increasing sedation of patients in successful fibrotic bronchoscopy with minimal sedative medication and minimal respiratory and cardiac complications

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 1-2 on 70 patients. Block randomization method was used for randomization.

Settings and conduct
A double-blind clinical trial study on 70 male and female patients who are candidates for fiberoptic bronchoscopy at Sina Hospital in Tehran. The patients are divided into intervention and control groups by block randomization method. Data analyst, outcome assessor, clinical caregiver and patients are not aware of the type of study drug.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 20-70 candidates for fiberoptic bronchoscopy under sedation.Exclusion criteria:Patients with a history of addiction and taking methadone, a history of taking neurologic and Psychiatric drugs, a history of allergy to diphenhydramine, a history of renal and liver failure, a history of cardiac ischemia and hemodynamic instability.

Intervention groups
Intervention group: 1mg/kg of diphenhydramine isinfused intravenously 10 minutes before bronchoscopy.Then, the same volume of normal saline as the control group is infused until the end of bronchoscopy . Control group: they receive 1 µg/kg over 10 minutes, and then receive continuous intravenous infusion at a rate of 0.5 µg/kg/h until the end of bronchoscopy. .

Main outcome variables
The degree of sedation at the beginning and minutes 2, 5, 10 and 15 of bronchoscopy, the amount of propofol boluses in cases of insufficient sedation, the length of the procedure and side effects such as cardiac arrhythmia, hypoxemia, hemodynamic changes, nausea and vomiting and the duration of recovery are recorded.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130304012695N18**
Registration date: **2023-11-20, 1402/08/29**
Registration timing: **prospective**

Last update: **2023-11-20, 1402/08/29**
Update count: **0**

Registration date
2023-11-20, 1402/08/29

Registrant information
Name
mohammadreza khajavi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-12-21, 1402/09/30
Expected recruitment end date
2024-10-01, 1403/07/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Comparison of the sedative effects of diphenhydramine and dexmedetomidine in fiberoptic bronchoscopy of patients

Public title
Sedation in bronchoscopy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All candidates for fiberoptic bronchoscopy aged 20-70 years who need sedation
Exclusion criteria:
Patients who have a history of drug addiction or are taking methadone Patients who take neurologic or psychoactive drugs Patients with a history of renal and liver failure History of allergy to diphenhydramine History of ischemic heart disease Patients with hemodynamic instability
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize patients Block balanced randomization is used. Before studying, one of the person who is not a member of the research team performs the randomization process by using Random generator software, forms blocks with size of 4 for the intervention and control groups. The complete cards of blocks are given to the head of the operative room, who is unaware of the study process in an envelope and one card is given to each patient before starting intubation process
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients participating in the research are not aware of the type of sedation for bronchoscopy. The name of the person responsible for collecting research data is not in the list of researchers. The clinical care person also does not know about the research groups. The data analyst is not involved in the research process.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Sina Hospital - Tehran University of Medical Sciences
Street address
Sina Sospital, Imam Khomeini st.
City
Tehran
Province
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Postal code
1136746911
Approval date
2023-11-12, 1402/08/21
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1402.101

Health conditions studied

1

Description of health condition studied
Sedation for bronchoscopy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The degree of sedation and agitation
Timepoint
At the beginning and 2, 5, 10 and 15 minutes of bronchoscopy
Method of measurement
Based on the criteria of the Richmond Agitation Sedation Scale

2

Description
Amount of propofol boluses in cases of insufficient sedation
Timepoint
Agitation degree greater than one during bronchoscopy
Method of measurement
At the end of bronchoscopy based on mg

3

Description
Hemodynamic indicators ,heart rate and blood pressure
Timepoint

Before drug induction and 5, 10 and 15 minutes after starting bronchoscopy and during recovery

Method of measurement

From patient monitoring

4

Description

Hypoxemia

Timepoint

During bronchoscopy

Method of measurement

By pulse oximetry

5

Description

Recovery time

Timepoint

From the end of bronchoscopy to the time of leaving the bronchoscopy department

Method of measurement

By the Chronometer based on minutes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 ml of normal saline containing 1 mg/kg diphenhydramine (manufactured by Raha Pharma) is prepared with the help of an anesthetist according to the patient's grouping and is infused intravenously 10 minutes before bronchoscopy. The volume of the control group is prepared from normal saline and is infused at a constant rate until the end of the procedure.During bronchoscopy and recovery, information related to the target variables of the study will be collected. If the patients are restless during the procedure, propofol (manufactured by Pfizer) will be used to improve sedation.

Category

Treatment - Drugs

2

Description

Control group: 10 ml of normal saline containing 1 µg/kg of dexmedetomidine (manufactured by Darou Darman Arang factory) is prepared with the help of an anesthesiologist according to the grouping of the patient and is infused intravenously 10 minutes before bronchoscopy. Then a syringe of the same shape and volume The intervention group was prepared with normal saline and dexmedetomidine and was infused at a rate of 0.5 µg/kg/h until the end of the operation. If the patients are restless during the procedure, propofol (manufactured by Pfizer) will be used to improve sedation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Mohammad Reza Khajavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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

Tehran University of Medical Sciences

Proportion provided by this source

60

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
Tehran University of Medical Sciences
Full name of responsible person
Mohammadreza Khajavi
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
Main study outcome data
When the data will become available and for how long
Six months after the end of the study
To whom data/document is available
University and industry researchers
Under which criteria data/document could be used
Sharing experiences to increase the sedation of bronchoscopy patients
From where data/document is obtainable
Dr. Khajavi's email address is khajavim@tums.ac.ir
What processes are involved for a request to access data/document
Request by email and response within one month
Comments