

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 is infused 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1220

Email address

khajavim@tums.ac.ir

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

Tehran

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

Street address

Sina Hospital Imam khomeini st

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8550

Email

khajavim@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Akbari Sari

Street address

Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blvd.0

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email

vcr@tums.ac.ir

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
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6312 1220
Fax
+98 21 6312 0000
Email
khajavim@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadreza Khajavi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6312 1220
Fax
+98 21 6312 0000
Email
khajavim@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadreza Khajavi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6312 1220
Fax
+98 21 6312 0000
Email
khajavim@tums.ac.ir

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

