

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of Dextromethorphan premedication on cough, pain, anxiety, procedure duration and sedation during fiber optic bronchoscopy: a randomized, double-blind, placebo-controlled trial

Protocol summary

Summary

1. Objective: Patients are usually conscious during Fiber Optic Bronchoscopy (FOB), so their cooperation could strongly affect the procedure quality. 2. Design: Patients scheduled for FOB will be randomly assigned by research supervisor (using random number table) to group-A and group-B. Group-A patients will receive 90 mg syrup Dextromethorphan and group-B will receive syrup sucrose (as placebo). 3. Setting and conduct: Both group of patient will receive drug or placebo in similar container 90 min before diagnostic FOB. In addition to patients, researcher (who gathers the data) and the physician who performs and monitors the patients during FOB will not be aware of drug/placebo group. 4. Participants including major eligibility criteria: Inclusion 1- Any documented indication for diagnostic FOB; 2- Age>18; Exclusion: 1. Allergy to opioids; 2. Taking sedative drugs during last 48 hours; 3. Pregnant woman; 4. Breastfeeding; 5. Patients with central nervous system diseases; 6. Associated unstable medical condition; 7. Emergent FOB; 8. Unconsciousness patients; 9. Intubated patients. 5. Intervention: 90 min before FOB, patients will receive 90 mg (30 cc) of syrup Dextromethorphan (IRC-1228087158) of equivalent placebo (sucrose). 6. Main outcome measures (variables): -Cough intensity (mild, moderate, severe) during FOB assessed by physician -Anxiety (mild, moderate, severe) during FOB assessed by patient -Lidocaine requirement (dose) during FOB assessed by physician -Midazolam requirement (dose) during FOB assessed by physician - Fentanyl requirement (dose) during FOB assessed by physician -General perception about procedure (mild, moderate, severe) during and 2 hours after FOB assessed by patient -Duration of FOB

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060520024N2**

Registration date: **2015-07-06, 1394/04/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-06, 1394/04/15

Registrant information

Name

Soheil Peiman

Name of organization / entity

Tehran University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2015-06-01, 1394/03/11

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Dextromethorphan premedication on cough, pain, anxiety, procedure duration and sedation during fiber optic bronchoscopy: a randomized, double-blind, placebo-controlled trial

Public title

The effect of Dextromethorphan premedication on cough, pain, anxiety, procedure duration and sedation during fiber optic bronchoscopy.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: 1- Any documented indication for diagnostic Fiber Optic Bronchoscopy; 2- Age>18;
Exclusion criteria: 1. Allergy to opioid drugs; 2. Taking sedative drugs during last 48 hours; 3. Pregnant woman; 4. Breastfeeding; 5. Patients with central nervous system diseases; 6. Patients with unstable medical condition; 7. Emergent Fiber Optic Bronchoscopy; 8. Impaired level of consciousness; 9. Intubated patients.

AgeFrom **18 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **66****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Sixty-six patients scheduled for FOB in Imamkhomeini hospital complex will be randomly allocated into two groups according to four blocks (AABB) randomization system. Six states of AABB, ABAB, ABBA, BBAA, BABA, and BAAB will be recorded in six different cards, and then these cards will be mixed together. Consequently, the cards will be selected for 18 times and the order of letters will be registered. The A and B label will be sealed to the researcher and the patients.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

6th floor, Vice Chancellor for Research, Tehran University of Medical Sciences central building, Keshavarz blvd. Ghods street.

City

Tehran

Postal code**Approval date**

2014-12-31, 1393/10/10

Ethics committee reference number

9111160015-131784

Health conditions studied**1****Description of health condition studied**

Respiratory disorder, unspecified

ICD-10 code

J98.9

ICD-10 code description

Respiratory disease (chronic) NOS

Primary outcomes**1****Description**

Cough intensity

Timepoint

during FOB

Method of measurement

Physicians' self assessment score

2**Description**

Anxiety intensity

Timepoint

during FOB

Method of measurement

Patients' self assessment score

3**Description**

Lidocaine requirement

Timepoint

during FOB

Method of measurement

Dose of drug recorded by Physician

4**Description**

Midazolam requirement

Timepoint

during FOB
Method of measurement
Dose of drug recorded by Physician

5

Description
Fentanyl requirement
Timepoint
during FOB
Method of measurement
Dose of drug recorded by Physician

6

Description
General perception about procedure
Timepoint
during FOB
Method of measurement
Patients' self assessment score

Secondary outcomes

1

Description
General perception about procedure
Timepoint
2 hours after FOB
Method of measurement
patients' self-assessment score

2

Description
Duration of FOB
Timepoint
at the end of FOB
Method of measurement
time in minutes

Intervention groups

1

Description
Ninety minutes before FOB, 90 mg (30 cc) of syrup
Dextromethorphan, manufactured by kharazmi
pharmaceutical co, code:IRC-1228087158,
Category
Treatment - Drugs

2

Description
Ninety minutes before FOB, 30cc sucrose syrup
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imamkhomeini hospital, Tehran University of Medical
Sciences
Full name of responsible person
Dr. Soheil Peiman
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Gharib Street, End of Keshavarz blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of
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Full name of responsible person
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Vice chancellor for research, 6th Floor, Central
organization of Tehran University of Medical Sciences,
Ghods street, Keshavaez blv,
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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
Vice chancellor for research, Tehran University of Medical
Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Assistant professor
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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty