

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of albuterol spray-on hypoxia and bronchospasm in patients with chronic obstructive pulmonary disease (COPD) under general anesthesia

Protocol summary

Study aim

Determination of the effect of albuterol spray-on hypoxia and bronchospasm in patients with chronic obstructive pulmonary disease (COPD) under general anesthesia

Design

Participants in the study were assigned to the intervention (B) and control (A) groups by block randomization. In this way, using a dice that has 6 faces, the samples are assigned to their groups. A number is written on each side and each number is assigned to one of the blocks of the table, which has its own special mode. it shows. Group A (albuterol) and group B (no albuterol).

Settings and conduct

Operating room of 5 Azar Hospital in Gorgan

Participants/Inclusion and exclusion criteria

The patient is a smoker, ASA class 1 and 2 The disease is more than 35 years old The patient has a history of COPD

Intervention groups

Intervention group: The patient receives 2 puffs of albuterol spray (2.5 micrograms per puff) 20 minutes before anesthesia

Main outcome variables

Wheezing Bronchospasm Frequent coughing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170108031818N1**

Registration date: **2021-11-29, 1400/09/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-29, 1400/09/08**

Update count: **0**

Registration date

2021-11-29, 1400/09/08

Registrant information

Name

fatemeh mehravar

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 893 7199

Email address

mehravar10261@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-11-06, 1401/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of albuterol spray-on hypoxia and bronchospasm in patients with chronic obstructive pulmonary disease (COPD) under general anesthesia

Public title

The effect of albuterol spray on hypoxia and bronchospasm in patients with chronic obstructive pulmonary disease (COPD)

Purpose

Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient is a smoker ASA is class 1 and 2 The patient has a history of COPD
Exclusion criteria:
The patient develops bronchospasm during the operation The surgery lasted more than 3 hours Pulmonary artery pressure is greater than 25 mm Hg Changes in blood pressure, heart rate and drop in severity by 20% of baseline

Age
From **35 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants in the study were assigned to the intervention (B) and control (A) groups by block randomization. In this way, using a dice that has 6 faces, the samples are assigned to their groups. A number is written on each side and each number is assigned to one of the blocks of the table, which has its own special mode. it shows. Group A (albuterol) and group B (no albuterol).

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding in this study is double-blinding. So that both the patient did not know in which treatment group and the investigator (Investigator) were not aware of the patient's treatment group. The method of blinding was such that the esteemed supervisor filled the contents of the spray and the sprays were given to the anesthesia resident student who was the main presenter of the current dissertation. The evaluator, who was a resident student, did not know the contents of the sprays.

Placebo
Used

Assignment
Parallel

Other design features
-

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

shastkola blv. gorgan

City

gorgan

Province

Golestan

Postal code

4915789465

Approval date

2021-10-03, 1400/07/11

Ethics committee reference number

IR.GOUMS.REC.1400.272

Health conditions studied

1

Description of health condition studied

Chronic pulmonary obstruction(COPD)

ICD-10 code

J44. 9

ICD-10 code description

J44. 9

Primary outcomes

1

Description

wheezing

Timepoint

once. After intubation of the endotracheal tube

Method of measurement

Using a medical earphone, the patient's lungs can be heard

2

Description

Frequent coughing

Timepoint

2 times - before anesthesia and after ecstasy

Method of measurement

By observing the appearance of the patient

3

Description

Bronchospasm

Timepoint

1 time. After anesthesia

Method of measurement

If the patient is intubated, bronchospasm is suspected by the anesthesia ventilator storage bag if the storage bag tightens and is considered positive and recorded.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient receives 2 puffs of albuterol spray (2.5 micrograms per puff) 20 minutes before anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

5AZAR HOSPITAL IN GORGAN

Full name of responsible person

Mohrokh Maddah

Street address

5 Azar St., Gorgan

City

gorgan

Province

Golestan

Postal code

4915789465

Phone

+98 17 3217 7419

Email

mehravar10261@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

mahrokh maddah

Street address

5 Azar St., Gorgan

City

gorgan

Province

Golestan

Postal code

4915789465

Phone

+98 17 3217 7419

Email

mehravar10261@goums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

mahrokh maddah

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

5 Azar St., Gorgan

City

gorgan

Province

Golestan

Postal code

4915789465

Phone

+98 17 3217 7419

Email

mehravar10261@goums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

mahrokh maddah

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

5 Azar St., Gorgan

City

gorgan

Province

Golestan

Postal code

4915789465

Phone

+98 17 3217 7419

Email

mehravar10261@goums.ac.ir

Phone

+98 17 3217 7419

Email

Mehravar10261@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

seyed mahrokh maddah

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

5azar street

City

gorgan

Province

Golestan

Postal code

4915789465

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

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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