

# 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

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#### Province

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#### Postal code

4915789465

#### Phone

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#### 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

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**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