

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the Impact of Applying Ipratropium Bromide Inhalation on Cough Following Bronchoscopy in Children

Protocol summary

Study aim

Investigating the Impact of Applying Ipratropium Bromide Inhalation on Cough Following Bronchoscopy in Children

Design

the collection of data is known as the field and the questionnaire and interview are used. That way, 60 qualified children are tested using the permutation blocks to two testing and control groups, 30 in the test group and 30 in the control group.

Settings and conduct

This study is a clinical trial without blindness. The study is conducted on the children of the educational and therapeutic center of namazi affiliated to the Shiraz University of Medical Sciences. The population studied by the children referred to the Shiraz namazi Hospital under the auspices of Bronchoscopy

Participants/Inclusion and exclusion criteria

The inclusion criteria include the age between 2 and 12 years and under Bronchoscopy . The exit criteria include the use of inhalation and oral corticosteroids, heart disease, drug sensitivity, and the existence of smoking and smoking in the family

Intervention groups

The control group is placed under standard care and medication before and after treatment, and in addition to the standard care group, 2 for 3 minutes for the 3 dose of inhalation bromide by damyar, the control group will be carried out by damyar an hour before and the control group is interviewed in terms of the extent of the coughing.

Main outcome variables

number and severity of cough, respiratory rate, heart rate and blood pressure, need for suction during surgery and after entering recovery

General information

Reason for update

Acronym

SIIBCS

IRCT registration information

IRCT registration number: **IRCT20211028052894N1**

Registration date: **2022-06-13, 1401/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-13, 1401/03/23**

Update count: **0**

Registration date

2022-06-13, 1401/03/23

Registrant information

Name

Mohamad amin Tavazo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3632 1496

Email address

ehsantavazo@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-26, 1400/12/07

Expected recruitment end date

2022-07-29, 1401/05/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of Applying Ipratropium Bromide Inhalation on Cough Following Bronchoscopy in Children

Public title

Investigating the Impact of Applying Ipratropium Bromide Inhalation on Cough Following Bronchoscopy in Children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The inclusion criteria include the age between 2 and 12 years The inclusion under Bronchoscopy

Exclusion criteria:

The exit criteria include the use of Inhalation and oral corticosteroids, heart disease, drug sensitivity, and the existence of smoking and smoking in

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

the data collection method is a field and questionnaire and interview is used. In this study, children in this study will be divided into two testing and control groups, 30 in the test group and 30 in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

according to the limited society and lack of similar study, the pilot sampling method is used to determine sample size, as it is intended for the control group of 30 and for the test group of 30.

Secondary Ids

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

west sheykhi

City

shiraz

Province

Fars

Postal code

7185998181

Approval date

2021-10-20, 1400/07/28

Ethics committee reference number

IR.SUMS.MED.REC.1400.380

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

Investigating the Impact of Applying Ipratropium Bromide Inhalation on Reducing Cough Following Bronchoscopy in Children

ICD-10 code

0BJ08ZZ

ICD-10 code description

Inspection of Tracheobronchial Tree, Via Natural or Artificial Opening Endoscopic

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

number cough

Timepoint

The recovery and immediately after the patient " s arrival at the recovery, then every 30 minutes will be assessed number of coughs .

Method of measurement

count number of coughs by nurse

Secondary outcomes**1****Description**

Respiratory rate

Timepoint

During and immediately after finishing the work and entering the patient to the recovery is remembered every 30 minutes

Method of measurement

Measures and notes at the specified times by the nurse

2**Description**

Heart rate

Timepoint

During and immediately after finishing the work and entering the patient to the recovery is remembered every 30 minutes

Method of measurement

Measures and notes at the specified times by the nurse

3**Description**

Blood pressure

Timepoint

During and immediately after finishing the work and entering the patient to the recovery is remembered every 30 minutes

Method of measurement

Measures and notes at the specified times by the nurse

4

Description

The need for suctioning

Timepoint

During and immediately after finishing the work and entering the patient to the recovery is remembered every 30 minutes

Method of measurement

Measures and notes at the specified times by the nurse

Intervention groups

1

Description

Intervention group: First, 30 eligible kindergartens will be selected as the intervention group using permutation blocks. In addition to standard care, 2 puffs will be performed every 20 minutes for 3 ipratropium bromide inhaled by Demiar one hour before surgery and will be interviewed and observed in terms of coughing rate. For this purpose, a nurse colleague without knowing the prescription of the drug is requested to remember the severity and number of coughs, the number of breathing, heart rate and blood pressure of the patient at the specified times during and immediately after the completion of the work and the patient's entry into the recovery every 30 minutes. Also, the need for suctioning during surgery and after the patient's arrival to recovery at similar times should be remembered.

Category

Treatment - Drugs

2

Description

Control group: 30 eligible kindergartens will be selected as the control group using permutation blocks, the control group will be treated with standard care and medications before, during and after bronchoscopy and will be interviewed and observed in terms of cough rate. For this purpose, a nurse colleague is requested without the knowledge of the prescription of the drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Mohammad Ashkan Moslehi

Street address

West Zand; Namazi Hospital

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Shiraz

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7193613311

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namazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammdi

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Amin Tavazo
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not 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

no data

When the data will become available and for how long

no data

To whom data/document is available

no data

Under which criteria data/document could be used

no data

From where data/document is obtainable

no data

What processes are involved for a request to access data/document

no data

Comments