Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of salbutamol administration by inhalation together with rapid and deep breathing in comparison with the standard method: A clinical trial

Protocol summary

Study aim
Determining the effect of salbutamol administration by inhalation together with rapid and deep breathing without coordination in the treatment of acute obstructive pulmonary diseases. 1) Determination and comparison of mean PEF 5 minutes after starting treatment in the intervention and standard treatment groups; 2) Determination and comparison of mean PEF 10 minutes after starting treatment in the intervention and standard treatment groups; 3) Determination and comparison of mean PEF 15 minutes after starting treatment in the intervention and standard treatment groups.

Design
Clinical trial

Settings and conduct
Patients 15–75 years of age who visit the emergency department of Shahid Sadoughi Hospital in Yazd, Iran, due to bronchospasm caused by inhalation, asthma, or COPD. The patient is asked to breathe rapidly and deeply during medication inhalation. Three puffs are given in rapid succession with 1-second intervals. After 10-15 minutes, three more puffs are given in the same way. A peak flow meter is used to assess the patient's response to the inhalation method at 0, 5, 10, and 15 minutes after treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients 15–75 years of age who visit the emergency department of Shahid Sadoughi Hospital in Yazd, Iran, due to bronchospasm caused by inhalation, asthma, or COPD. Lack of severe respiratory distress and absence of other underlying diseases that require treatments other than inhaled salbutamol. Exclusion criteria: 1) Patients who need treatments other than salbutamol, such as atrovent, combivent, or pulmicort; 2) Patients who visit the emergency department with signs of respiratory failure, including acrocyanosis, PO2 below 60 mmHg, or PCO2 above 80 mmHg

Intervention groups
Patients who visited Shahid Sadoughi Hospital and needed salbutamol inhaler therapy

Main outcome variables
peak expiratory flow

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171231038154N1**
Registration date: **2018-08-17, 1397/05/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-17, 1397/05/26**
Update count: **0**

Registration date
2018-08-17, 1397/05/26

Registrant information

Name
Ebrahim Akbarzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 56 3278 2686

Email address
dr.akbarzadeh@bums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-05, 1397/03/15

Expected recruitment end date

2018-09-01, 1397/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of salbutamol administration by inhalation together with rapid and deep breathing in comparison with the standard method: A clinical trial

Public title

The effect of salbutamol administration by inhalation together with rapid and deep breathing in comparison with the standard method: A clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 15–75 years of age who visit the emergency department of Shahid Sadoughi Hospital in Yazd, Iran, due to bronchospasm caused by inhalation, asthma, or COPD. Lack of severe respiratory distress and absence of other underlying diseases that require treatments other than inhaled salbutamol.

Exclusion criteria:

Patients who need treatments other than salbutamol, such as atrovent, combivent, or pulmicort; Patients who visit the emergency department with signs of respiratory failure, including acrocyanosis, PO2 below 60 mmHg, or PCO2 above 80 mmHg

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants were made aware that there were two different methods of salbutamol administration. However, they did not know to which group they belonged. Data analysis was performed using coded data and the analyzer had no knowledge of the particular group for each code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University Campus, School of Medicine, Prof. Hesabi Blvd.

City

Yazd

Province

Yazd

Postal code

891513149

Approval date

2016-10-19, 1395/07/28

Ethics committee reference number

IR.SSU.MEDICINE.REC.1395.181

Health conditions studied

1

Description of health condition studied

DYSPNEA

ICD-10 code

J39.3

ICD-10 code description

Upper respiratory tract hypersensitivity reaction, site unspecified

Primary outcomes

1

Description

peak expiratory flow

Timepoint

0, 5min, 10min, 15min

Method of measurement

peak flow meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient is asked to breathe rapidly and deeply during medication inhalation. Three

puffs are given in rapid succession with 1-second intervals. After 10-15 minutes, three more puffs are given in the same way. A peak flow meter is used to assess the patient’s response to the inhalation method at 0, 5, 10, and 15 minutes after treatment.

Category

Treatment - Devices

2

Description

Control group: In this group, the patients are treated according to the standard method for salbutamol inhaler administration: The inhaler is placed near the patient’s mouth or between the patient’s teeth. The patient is instructed to inhale slowly simultaneous with inhaler administration, hold his/her breath for ten seconds, and then exhale. Six inhaler puffs are given, and a peak flow meter is used to assess the patients' response to the inhalation method at 0, 5, 10, and 15 minutes after treatment.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital, Yazd, Iran

Full name of responsible person
Ebrahim Akbarzadeh

Street address
Shahid Sadoughi Hospital, Shahid Ghandi Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Vice-President for Research, Yazd University of Medical Sciences

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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Ebrahim Akbarzadeh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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