

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison the effect of salbutamol via nebulizer, spray with and without spacer on pulmonary function in Chronic Obstructive Pulmonary Disease (COPD)

Protocol summary

Lung function "lung volumes and capacities"

Study aim

Comparison the effect of salbutamol via nebulizer, spray with and without spacer on pulmonary function in chronic obstructive pulmonary disease (COPD)

Design

The clinical trial with parallel and randomized groups with time series design and measurements will be made at reasonable intervals (based on scientific texts) and consecutively.

Settings and conduct

The research area will be the Shohada hospitals in Qaen. In this clinical trial study, 66 patients with COPD will be selected and randomly allocated in three groups of Sprays, Spacer, and Nebulizer by the method of 6-permutation blocks. Before the intervention, lung function indicators will be measured using a spirometry device, the respiratory rate, and the percentage of oxygen saturation of the blood using a pulse oximetry device. Then patients will be given in one group Salbutamol by spray, patients in the second group Salbutamol through a spacer, and the third group Salbutamol through nebulizer. Then, 15, 30, 60, and 90 minutes later, spirometry will be performed again and respiratory indicators will be determined. This will be done on two consecutive days.

Participants/Inclusion and exclusion criteria

Patients with COPD between the ages of 40 and 75 who are alert and able to speak and communicate and do not have underlying diseases such as diabetes and kidney and heart failure, etc., and the spirometry test has a ratio of $0.7 > FEV1 / FVC$.

Intervention groups

Then patients in first group will be given Salbutamol by spray, patients in the second group Salbutamol through Spacer and the third group Salbutamol through Nebulizer.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200228046634N1**

Registration date: **2021-05-15, 1400/02/25**

Registration timing: **retrospective**

Last update: **2021-05-15, 1400/02/25**

Update count: **0**

Registration date

2021-05-15, 1400/02/25

Registrant information

Name

Maryam Derogar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of salbutamol via nebulizer, spray with and without spacer on pulmonary function in Chronic Obstructive Pulmonary Disease (COPD)

Public title

The effect of salbutamol on pulmonary volumes and capacities

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction to participate in research Abnormal spirometry test including $0.7 \geq FEV1/FVC$ ratio Age of 40-75 years old Physical ability to perform spirometry maneuvers Lack of pregnancy With body mass index between 18.5 - 25 Stages 1-4 of the disease based on GOLD criteria No specific intervention related to COPD or other possible diseases other than routine treatments Having awareness, the power of speech and communication Having a stable physiological state to answer questions No spirometry contraindications (uncontrolled blood pressure, infectious respiratory infection, active hemoptysis, recent eye or ear surgery, rupture of the tympanic membrane, recent history of CVA or pulmonary embolism, history of myocardial infarction or unstable angina in the last 6 weeks)

Exclusion criteria:

Severely ill patients with COPD exacerbation with loss of consciousness or need for intubation Patients with comorbidity disorders such as heart failure, kidney, liver and diabetes Asthma, pneumonia and severe respiratory failure with cyanosis and confusion

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The research units will be selected as available in terms of study entry criteria and will be randomly assigned to the three groups of sprays, spacer and nebulizer using triple permutation blocks. In this method, if we consider the spray group A, the spacer group B, and the nebulizer group C, the six possible states in the triple blocks will be ABC-BAC-BCA-ACB-CAB-CBA, Each of these blocks will be assigned a number(We determine the number assigned to each block and it starts from 1). These numbers will be poured into a container and one of these numbers will be removed randomly by drawing lots at the beginning of sampling. Based on the selected number and the corresponding block, patients will be included in the

study. After the arrival of the first three patients according to the designated block, a number was randomly removed from the container and sampling will continue.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The study has a time series design

Secondary Ids

empty

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

Ethics committee of Gonabad University of Medical Science

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad₉₉₉₉

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2020-01-27, 1398/11/07

Ethics committee reference number

IR.GMU.REC.1398.149

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

Chronic Obstructive Pulmonary Disease (COPD)

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

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

The pulmonary volumes and capacities

Timepoint

The Measurement of pulmonary volumes and capacities at the beginning of the study and 15, 30, 60 and 90 minutes after the beginning of the intervention

Method of measurement

Perform the spirometry test in two consecutive days

2

Description

The respiratory indicators

Timepoint

At the beginning of the study and 15, 30, 60 and 90 minutes after the beginning of the intervention

Method of measurement

The Respiratory Rate by counting the number of chest ups and downs and the percentage of oxygen saturation of the blood using the pulseoximetry device

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: receiving 200 micro grams of Salbutamol Equivalent to 2 puffs via Salbutamol spray under the Ventalex brand two minutes apart at a time.

Category

Treatment - Drugs

2

Description

The intervention group: receiving 200 micro grams of Salbutamol Equivalent to 2 puffs through Salbutamol spray under the Ventalex brand through spacer manufactured by Spadana Medical Technology Company two minutes apart at a time..

Category

Treatment - Drugs

3

Description

Intervention group: receiving 2.5 mg of Salbutamol solution of the Astalin brand through nebulizer type of ultrasound made by Rastak Medical Technology Company in one turn .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaen Shohada hospital

Full name of responsible person

Dr. Mohammad Reza Arefifar

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Shafa Street, Qaen Shohada hospital

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Sponsors / Funding sources

1

Sponsor

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Maryam Derogar

Position

Student

Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Potential data will be shared after unidentifiable individuals.

When the data will become available and for how long

Get started 8 months after the publication of results

To whom data/document is available

The researcher on academic institutions

Under which criteria data/document could be used

The information should not be changed.

From where data/document is obtainable

E-mail Maryam Derogar: dm.derogar72@gmail.com

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

The E-mail to the given address and provide sufficient and acceptable information. Information will be given if data is acceptable.

Comments