# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

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

## Protocol summary

**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**

Lung function "lung volumes and capacities"

## 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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**Email address**

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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≥ 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, Gonabadووو
**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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## Sponsors / Funding sources

**1**

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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**
Bachelor
**Other areas of specialty/work**

Nursery
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**
derogar.m.stu@gmu.ac.ir

## 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**