

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison The Effect of Ventolin Nebulizer With And Without Hypertonic Saline % 3 On Dyspnea In Patients With Chronic Obstructive Pulmonary Disease

Protocol summary

Study aim

Comparison Of The Effect Of Ventolin Nebulizer With And Without Hypertonic Saline 3% On Dyspnea In Patients With Chronic Obstructive Pulmonary Disease

Design

A randomized trial with two intervention and control groups single-blind clinical Randomized, 64 patients with COPD

Settings and conduct

Allameh Bohlool Gonabadi Hospital - Blinding technique: The questionnaire will be completed by a person who will not be aware of allocation of patients to control or intervention groups. Patients will be randomly divided into intervention and control groups. For control group Ventolin plus 5 cc distilled water and for intervention group, Ventolin plus 5 cc hypertonic saline 3% will be administered. Shortness of breath will be assessed before and after the intervention using borg scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willing to participate in the research The patient is alert Patients are known to be COPD or admitted with this diagnosis. Patients with dyspnea on the Borg scale greater than 3 Ventolin nebulizer is prescribed for the patient Exclusion criteria: Pregnancy; Nausea and vomiting; Intolerance to the mask used for inhalation therapy.

Intervention groups

Distilled water and 3% hypertonic saline

Main outcome variables

Dyspnea before and after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181205041858N1**

Registration date: **2019-10-16, 1398/07/24**

Registration timing: **retrospective**

Last update: **2019-10-16, 1398/07/24**

Update count: **0**

Registration date

2019-10-16, 1398/07/24

Registrant information

Name

Azam Razizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5723 6833

Email address

razizadeh.a@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-26, 1397/11/06

Expected recruitment end date

2019-05-27, 1398/03/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison The Effect of Ventolin Nebulizer With And Without Hypertonic Saline % 3 On Dyspnea In Patients With Chronic Obstructive Pulmonary Disease

Public title

Comparison The Effect of Ventolin Nebulizer With And Without Hypertonic Saline% 3 On Dyspnea In Patients With Chronic Obstructive Pulmonary Disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Participate in research. Be alert Be known to be COPD or hospitalized with this diagnosis Have moderate or high dyspnea (at least scale 3 of the bourgeois scale)
 Nebulizer Ventolin in patient medication orders which have been ordered by a Internal specialist.
Exclusion criteria:
 Patient's death or decreased level of consciousness during treatment After diagnosis, the patient's shortness of breath is due to myocardial infarction, myocardial infarction, or congestive heart failure. Patient's unwillingness to continue research

Age
From **19 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Outcome assessor

Sample size
 Target sample size: **46**
 More than 1 sample in each individual
 Number of samples in each individual: **23**
 The research samples will be from the referrals to Allame Bohlool Gonabadi Hospital, which will be studied by the specialist with a history of COPD or diagnosis and will be randomly assigned to two groups.

Randomization (investigator's opinion)
Randomized

Randomization description
 Samples will be divided into two experimental and control groups based on permutation blocks (blocks of size 4). It will be listed according to six possible ways (AABB, ABAB, ...) randomly and the arrangement of receiving intervention will be determined accordingly. For blinding the questionnaire will be completed by a person who is not aware of the research unit in the control group or the experimental group.

Blinding (investigator's opinion)
Single blinded

Blinding description
 Participants in research and researcher are aware of the research, but the results evaluator is not aware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

ir.gmu.rec.1397.092

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

dyspnea

Timepoint

Before and 24, 48 hours after intervention

Method of measurement

Borg scale

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive Ventolin plus 5 cc hypertonic saline 3% at intervals of 6 hours as a nebulizer .hypertonic saline 3% at intervals of 6 hours as a nebulizer.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive Ventolin plus 5 cc distilled water at intervals of 6 hours as a nebulizer.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational, Research, Hospital, Allameh Behnollah
Gonabadi

Full name of responsible person

Azam Razizadeh

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Deputy of Research of Gonabad University of Medical
Sciences

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Web page address

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

Azam Razizadeh

Position

Master of Internal Surgery Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Mehdi Basiri Moghadam

Position

P.h.D. Student-based Research and faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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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