

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of hospitalization time with deoulin nebulizer, deoulin nebulizer with inhalation spray and deoulin nebulizer and pulmicort simultaneously in patients with chronic obstructive pulmonary disease in the disease exacerbation stage

Protocol summary

Study aim

Comparison of hospitalization time with deoulin nebulizer, deoulin nebulizer with inhalation spray and deoulin nebulizer and pulmicort simultaneously in patients with COPD

Design

This is a parallel randomized controlled clinical trial that will be performed on 174 patients with chronic obstructive pulmonary disease. Randomization in this research is done using quadri blocks using syntax written in SPSS program.

Settings and conduct

This study will conduct as a clinical trial study with 174 patients who will refer to Imam Hossain Hospital of Shahroud.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 80 years; patients with confirmed diagnosis of chronic obstructive pulmonary disease by spirometric and clinical findings and conscious consent to participate in research. Exclusion criteria: Loss of consciousness; severe respiratory distress with oxygen pressure less than 60 mm Hg and carbon dioxide pressure greater than 45 mm Hg in a venous gas sample; existence of severe infectious diseases of the respiratory tract for at least one month.

Intervention groups

For the first intervention group, deoulin nebulization in a 2.5 ml vial every 20 minutes once to three times with salbutamol and atrovent sprays 8 puffs and repeat both sprays up to three times every 20 minutes with the use of asmyar will be prescribed. For the second intervention group, deoulin nebulization (salbutamol + ipratropium bromide) in a 2.5 ml vial every 20 minutes once to three times with a half-milligram Pulmicort vial every 20 minutes for three times will be prescribed and

for the control group, 2.5 ml deoulin nebulization will be prescribed in the first stage and repeated every 20 minutes up to three times.

Main outcome variables

The amount of hospitalization hours in the emergency department and Measuring the extent of disease severity reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210830052333N1**

Registration date: **2021-10-13, 1400/07/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-13, 1400/07/21**

Update count: **0**

Registration date

2021-10-13, 1400/07/21

Registrant information

Name

maryam khodayar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hospitalization time with deoulin nebulizer, deoulin nebulizer with inhalation spray and deoulin nebulizer and pulmicort simultaneously in patients with chronic obstructive pulmonary disease in the disease exacerbation stage

Public title

Comparison of hospitalization time of patients with different treatments of deoulin nebulizer, deoulin nebulizer with inhalation spray and deoulin nebulizer and pulmicort simultaneously in patients with chronic obstructive pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18 to 80 years; Patients with confirmed diagnosis of chronic obstructive pulmonary disease by spirometric and clinical findings; Chronic illness for at least the last six months; Do not take any antibiotics for at least the last month; Conscious consent to participate in research.

Exclusion criteria:

Loss of consciousness; Severe restlessness; Severe respiratory distress with oxygen pressure less than 60 mm Hg and carbon dioxide pressure greater than 45 mm Hg in a venous gas sample; Severe heart failure; Pulmonary embolism; Use of any opium in the past month; Existence of severe infectious diseases of the respiratory tract for at least one month; History of any surgery on the respiratory tract.

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **174****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients were allocated to two intervention groups and one control groups according to random allocation table that illustrated by a statistician. Randomization was done using permuted block randomization method (Block size was 4) using blocked random allocation syntax in SPSS software. For calculation sample size was 174 and

number of blocks was 44. Allocation concealment was done using closed opaque envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahroud University of Medical Sciences

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Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

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Semnan

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3616611151

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.SHMU.REC.1399.029

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

Chronic obstructive pulmonary disease

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with (acute) exacerbation

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

The amount of hospitalization hours in the emergency department

Timepoint

Once an hour

Method of measurement

Count the hours of hospitalization

2

Description

Measuring the extent of disease severity reduction

Timepoint

Once an hour

Method of measurement

By counting the number of breaths per minute

3

Description

Maximum expiratory volume per the first second (FEV1)

Timepoint

Once an hour

Method of measurement

Micromedical spirometer

Secondary outcomes

1

Description

Measurement of arterial blood oxygen saturation

Timepoint

Once an hour

Method of measurement

Arterial blood oxygen measurement test with ABG device

2

Description

Measurement of venous blood carbon dioxide saturation

Timepoint

Once an hour

Method of measurement

Carbon dioxide test with ABG device

Intervention groups

1

Description

Intervention group 1: For the first intervention group, in addition to routine treatments including oxygen therapy, deoulin nebulization (salbutamol + ipratropium bromide) in a 2.5 ml vial every 20 minutes once to three times with salbutamol and atrovent sprays 8 puffs and repeat both sprays up to three times every 20 minutes with the use of asmyar will be prescribed .

Category

Treatment - Drugs

2

Description

Intervention group 2: For the second intervention group, in addition to routine treatments including oxygen therapy, deoulin nebulization (salbutamol + ipratropium bromide) in a 2.5 ml vial every 20 minutes once to three times with a half-milligram Pulmicort vial every 20 minutes for three times will be prescribed .

Category

Treatment - Drugs

3

Description

Control group: For the control group, in addition to routine treatments including oxygen therapy, 2.5 ml deoulin nebulization will be prescribed in the first stage and repeated every 20 minutes up to three times.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital of Shahroud

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor for research; Shahroud University medical and 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
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Full name of responsible person
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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

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

No - There is not 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