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.
Age
From **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
Street address
Shahroud University of Medical Sciences; 7 Tir squer, Shahroud
City
Shahroud
Province
Semnan
Postal code
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
Dr. Maryam khodayar
Street address
Imam Hossein Hospital., End Imam street., Shahroud , Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hassan Emamian
Street address
Vice chancellor for research; Shahroud University medical Sciences ,7th Tir squar, Shahroud
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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
Shahroud University of Medical Sciences

Full name of responsible person
Parisa Soleymani

Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

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Specialist

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Emergency Medicine

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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