Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of nebulized Furosemide in Chronic Obstructive Pulmonary Disease exacerbation patients.

Protocol summary

Study aim
The effect of nebulized furosemide on spirometric indexes in Chronic Obstructive Pulmonary Disease exacerbation patients

Design
A clinical trial with a control group was randomized with parallel, blind, and randomized groups.

Settings and conduct
This is a randomized clinical trials that was performed in COPD exacerbation patients in the year 1399 to 98 referred to emergency department of Imam Khomeini Hospital in Sari. Patients are randomly divided into two groups.The randomized method is Numbered drug containers. Doctor prescribing medications and patients, and analyst is not aware of the type of prescription drug. Spirometery are performed for two groups before prescribing drugs, 30 minutes and one hour after administration.

Participants/Inclusion and exclusion criteria
This is a triple-blind randomized clinical trial that was performed in COPD exacerbation patients in the year 1399 to 98 referred to emergency department of Imam Khomeini Hospital in Sari. Inclusion criteria include COPD exacerbation and FEV1/FVC ratio of less than 70% and no need for ventilator. Exclusion criteria include increased FEV1 of more than 200cc or 12% after salbutamol administration in spirometry, history of recent infectious diseases, rheumatoid arthritis, degenerative joint disease, vasculitis, and The probability of malignancy is based on the examination.

Intervention groups
The case group received 40 mg of furosemide (Chemidarou Industrial Company, Tehran, Iran, 20 mg/2 cc) in a 15-minute period. The control group received 4 ml of normal saline serum of 0.9% as an nebulized in 15 minutes. The Omron NE-C900 is used to produce the incense. For both groups, 5 mg salbutamol is administered as an nebulized for 15 minutes and 125 mg methyl prednisolone.

Main outcome variables
FEV1, FVC, FEV1 / FVC , PEFR , complications

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190109042305N1**
Registration date: **2019-01-25, 1397/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-25, 1397/11/05**
Update count: **0**

Registration date
2019-01-25, 1397/11/05

Registrant information
Name
Mir Saeid Ramezani
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 3336 1700
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-22, 1397/06/31
Expected recruitment end date
2019-04-19, 1398/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of nebulized Furosemide in Chronic Obstructive Pulmonary Disease exacerbation patients.

Public title
nebulized Furosemide and spirometric indexes in Chronic Obstructive Pulmonary Disease exacerbation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
COPD exacerbation patients FEV1/FVC less than 70% No need for ventilator

Exclusion criteria:
FEV1 Increase greater than 200 cc or 12% after salbutamol administration in spirometry The history of infectious diseases such as tuberculosis, recent respiratory infections, bronchiectasis and acute or chronic diarrhea Probability of malignancy based on examination Rheumatic arthritis, degenerative joint disease, vasculitis

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **47**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method is Numbered drug containers. So that the drugs of each group are already in the boxes of the same shape, color, size and weight and are completely sealed and Encoding becomes A and B. Doctor prescribing medications and patients with prescription drugs (furosemide and placebo) are unaware. To collect data, a questionnaire was prepared and pre-coded according to A and B and randomly placed in a folder.The nurse will use the package of treatment for each patient based on the leaflet taken from this folder (randomly).

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drugs of each group are already in the boxes of the same shape, color, size and weight and are completely sealed and Encoding becomes A and B. Doctor prescribing medications and patients with prescription drugs (furosemide and placebo) are unaware. To collect data, a questionnaire was prepared and pre-coded according to A and B and randomly placed in a folder.The nurse will use the package of treatment for each patient based on the leaflet taken from this folder (randomly).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Imam Khomeini Hospital Amir Mazandarani Street Sari

City
Sari

Province
Mazandaran

Postal code
4816633131

Approval date
2018-06-26, 1397/04/05

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1397.1408

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease exacerbation

ICD-10 code
J44.1

ICD-10 code description
Chronic obstructive pulmonary disease with (acute) exacerbation

Primary outcomes

1

Description
Forced expiratory volume in 1 second (FEV1)

Timepoint
Before prescribing medications, 30 minutes and one hour after administration

Method of measurement
spirometry

2

Description
Forced vital capacity

Timepoint
Before prescribing medications, 30 minutes and one hour after administration

Method of measurement
spirometry

Secondary outcomes

1

Description
Peak Expiratory Flow Rate
Timepoint
Before prescribing medications, 30 minutes and one hour after administration
Method of measurement
spirometry

2

Description
severity of respiratory distress
Timepoint
Before prescribing medications, as well as 30 minutes and one hour after administration
Method of measurement
Accessory muscle score

3

Description
adverse effect
Timepoint
Before prescribing medications, as well as 30 minutes and one hour after administration
Method of measurement
Patient evaluation

Intervention groups

1

Description
Intervention group: The case group received 40 mg of furosemide (Chemidarou Industrial Company, Tehran, Iran, 20 mg/2 cc) in a 15-minute period.
Category
Treatment - Drugs

2

Description
Control group: The control group received 4 ml of normal saline serum of 0.9% as an nebulized in 15 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Hospital
Full name of responsible person
Mir Saeid Ramezani
Street address
Imam khomeini Hospital, Amir Mazandarani street, Sari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeidi
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Imam khomeini Hospital, Amir Mazandarani street, Sari
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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
Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Mir Saeid Ramezani
Position
resident

Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
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Person responsible for updating data

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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
In this Study, all the Information on the main Outcome as well as the Side Effects are Shared
When the data will become available and for how long
The time to Start Accessing Data will be one Month after the Data is Printed
To whom data/document is available
The Data in this Study is Available to Researchers in Academic and Scientific Institutions as well as in Non-Related Fields.
Under which criteria data/document could be used
The Data is Available after Printing and the Specified time Period and is used to Improve the Scientific Level
From where data/document is obtainable
Dr Mir Saeid Ramezani .Email: mramezani@mazums.ac.ir
What processes are involved for a request to access data/document
This Data will be Available to the Applicant one Month after Printing
Comments