

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. Spirometry 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)

Phone

+98 11 3336 1700

Email address

mramezani@mazums.ac.ir

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,

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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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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 scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Mir Saeid Ramezani

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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