Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of adjunctive nebulized magnesium sulfate on symptoms and lung volumes, in patients presenting with acute exacerbation of chronic obstructive pulmonary disease

Protocol summary

Summary

1. Objectives: Acute exacerbation is a fact during natural course of chronic obstructive pulmonary disease (COPD) and the optimal treatments are still subject of ongoing researches. In this study we want to investigate the short term, in-hospital outcome of nebulized Magnesium sulfate in the terms of subjective and objective improvement in acute COPD exacerbation. 2. Design: Patients presented with acute COPD exacerbation will be randomly assigned (using random number table) to group-A and group-B. In addition to standard treatment, Group-A patients will receive Magnesium Sulfate by nebulizer mask and group-B will receive placebo. 3. Setting and conduct: Both group of patient will receive drug or placebo in similar container just before diagnostic tests. In addition to patients, researcher (who gathers the data) will not be aware of drug/placebo group. 4. Participants including major eligibility criteria: patients with known history of COPD presenting to emergency department with acute disease exacerbation will be included. Those with other associated medical disorders and unstable/uncooperative patients will be excluded. 5. Intervention: In addition to standard treatment, patients in drug / placebo group will receive 2.5 cc Magnesium Sulfate Vial 20% (Manufactured by Pasteur institute, IRC code: 1228054884) by nebulizer mask or 2.5 cc Sodium Chloride 0.9% (manufactured by Samen co. IRC code:1228065256) respectively. 6. Main outcome measures (variables): just before taking drug/placebo and again 90 minutes after that, the following variables will be checked: Lung volumes, Arterial oxygen saturation of hemoglobin and Persian version of CAT questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012420024N3**
Registration date: **2016-02-06, 1394/11/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-06, 1394/11/17

Registrant information

Name
Soheil Peiman
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-01-22, 1394/11/02

Expected recruitment end date

2016-03-22, 1395/01/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of adjunctive nebulized magnesium sulfate on symptoms and lung volumes, in patients presenting with acute exacerbation of chronic obstructive pulmonary disease

Public title
Nebulized magnesium sulfate treatment in acute exacerbation of chronic obstructive pulmonary disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1. Known history of chronic obstructive pulmonary disease (COPD) based on previous clinical history and spirometry; 2. Presentating to emergency department with at least two of following symptoms: shortness of breath, increase in the amount of sputum and/or purulent pattern of the sputum; 3. Age>40 years; 4. within 24 h of hospital admission; 5. smoking history > 20 pack.year; Exclusion Criteria: 1. Patient with unstable vital signs; 2. Intubated patient; 3. Associated comorbidity (pneumothorax, pulmonary embolism, pneumonia, acute coronary syndrome, congestive heart failure, neuromuscular disease, active malignancy and etc.); 4. Unconscious patient; 5. Inability to perform spirometry; 6. Nursing/pregnant women; 7. Previous history of allergy to magnesium sulfate;

Age
From **40 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of Tehran University of Medical Sciences

Street address
6th floor,Vice Chancellor for Research, Tehran University of Medical Sciences central building, Keshavarz blvd. Ghods street.

City
Tehran

Postal code

Approval date
2015-01-03, 1393/10/13

Ethics committee reference number
9111160025-129558

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease with acute exacerbation

ICD-10 code
J44.1

ICD-10 code description
Chronic obstructive pulmonary disease with acute exacerbation, unspecified

Primary outcomes

1

Description
Lung volumes

Timepoint
Just before the Magnesium Sulfate/Placebo and again after 90 minutes of administration

Method of measurement
COSMED spirometer

2

Description
Arterial oxygen saturation of hemoglobin

Timepoint
Just before the Magnesium Sulfate/Placebo and again after 90 minutes of administration

Method of measurement
Pulse oximeter - Beurer

3

Description
COPD Assessment Test (CAT) questionnaire, persian version

Timepoint
Just before the Magnesium Sulfate/Placebo and again after 90 minutes of administration

Method of measurement
CAT score

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

Discharge documents

Method of measurement

Days of admission

Intervention groups

1

Description

- Drug: 2.5 cc Magnesium Sulfate Vial 20% (Manufactured by Pasteur institute, IRC code: 1228054884) by nebulizer mask, just after performing the tests,

Category

Treatment - Drugs

2

Description

- Placebo:2.5 cc Sodium Chloride 0.9% (manufactured by Samen co. IRC code:1228065256)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamkhomeini hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr. Soheil Peiman

Street address

Gharib Street, End of Keshavarz blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Javad Mousavi

Street address

6th Floor, Central organization of Tehran university of medical sciences, Ghods street, Keshavaez blv, Tehran Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Internal medicine, Tehran university of medical sciences

Full name of responsible person

Dr. Soheil Peiman

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Advanced Thoracic Research Center, Tehran University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty