Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of intravenous magnesium sulphate as an adjuvant in the treatment of acute exacerbations of COPD in adults

Protocol summary

Study aim

To investigate the clinical benefits of IV MgSO4 as an adjuvant to standard treatment in patients with Acute exacerbation of COPD (AECOPD)

Design

Double blind randomized clinical trial with parallel groups in phase 3, with 41 cases in each group

Settings and conduct

The study was conducted at the emergency department of Imam Reza hospital, Mashhad. Iran. 80 Patients with acute exacerbation of COPD were randomly allocated to one of the two groups (MgSO4 or placebo) and received routine treatment. MgSO4 groups were given intravenous infusion of 2.5 g of MgSO4 (5 ml of 50% solution) in 50 mL of 0.9% normal saline and placebo group were given or 5 ml sterile water in 50 mL of 0.9% normal saline (placebo group). PEFR and Dyspnea severity score (using 10 point Likert scale) recorded after the first nebulization and 30 minutes after commencement of the last nebulization (90 minutes after ED presentation)

Participants/Inclusion and exclusion criteria

Enrollment: All adult patients with AECOPD who gave consent to participate and their PEFR was < 50% 20 minutes after the first dose of beta agonist. Excluded: need immediate endotracheal intubation or mechanical ventilation, hemodynamically unstable, uncooperative to perform peak flow meter, pregnant, other conditions contributing to dyspnea, such as pneumonia, pleural or pericardial effusion, pneumothorax, heart failure, renal failure, or any other serious medical conditions.

Intervention groups

group A (MgSO4 group) who received IV infusion of 2.5 g of MgSO4 in 50 mL of normal saline group B (placebo group) received 5 ml sterile water in 50 mL of normal saline

Main outcome variables

Primary outcomes: PEFR percent predicted and Dyspnea Severity Score at the end of treatment protocol (90 minutes after ED presentation). Secondary outcome: change in RR, SpO2, need for endotracheal intubation or noninvasive ventilation and ED discharge rate

General information

Reason for update

Because of some limitation in Conducting the study such as (but not limited to) not being able to buy a nebulizer and peak-flow meter on time, the study did not conduct at the arranged time. Tow years later that we started to perform the study and enroll the patient, we did some amendment was proposed by the methodologist which needs to be updated here.

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111519962N1**
Registration date: **2015-02-04, 1393/11/15**
Registration timing: **prospective**

Last update: **2020-04-14, 1399/01/26**
Update count: **1**

Registration date

2015-02-04, 1393/11/15

Registrant information

Name

Elham Pishbin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5312

Email address

pishbine@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date
2015-01-30, 1393/11/10
Expected recruitment end date
2015-08-01, 1394/05/10
Actual recruitment start date
2017-10-01, 1396/07/09
Actual recruitment end date
2018-04-01, 1397/01/12
Trial completion date
2018-04-01, 1397/01/12

Scientific title
The effect of intravenous magnesium sulphate as an adjuvant in the treatment of acute exacerbations of COPD in adults

Public title
The effect of intravenous magnesium sulfate in the treatment of patients with chronic obstructive pulmonary disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patient older than 18 years acute exacerbation of COPD
Exclusion criteria:
any other underlying causes for dyspnea including heart failure, asthma, renal failure, pneumothorax, pneumoni
Not willingness to participate
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Actual sample size reached: **77**
Randomization (investigator's opinion)
Randomized
Randomization description
We performed block randomization with a block size of 4 using a computer generated random sequence. This was administered by a third party process so that patients and researchers were unaware of allocation and randomly allocated patients to one of the two groups of the study. The MgSO4 group received vial A. The placebo group received vial B.
Blinding (investigator's opinion)
Double blinded
Blinding description
Daily, the chief nurse who was not involved in the patients' care blindly provided the MgSO4/placebo by filling similar vials, labeled A or B, with 5 mL MgSO4 (50% solution) or 5 mL sterile water. The MgSO4 group received vial A. The placebo group received vial B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Daneshgah Ave. Ghoreyshi building
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2014-11-22, 1393/09/01
Ethics committee reference number
922741

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, unspecified

Primary outcomes

1

Description
subjective improvement of dyspnea
Timepoint
First time after the initial dose of nebulized bronchodilator and second time after the treatment protocol (3 doses of bronchodilators and even Magnesium or placebo infusion)
Method of measurement
patient were asked about severity of dyspnea based on the 10 point likert scale

2

Description
Peak Expiratory Flow Rate(PEFR) improvement

Timepoint
First time after the initial dose of nebulized bronchodilator and second time after the treatment protocol (3 doses of bronchodilators and even Magnesium or placebo infusion)
Method of measurement
Peak-flow-metry

Secondary outcomes

1

Description
Intubation during the course of admition
Timepoint
any time during first 12 hours of admition
Method of measurement
Based on patients records

2

Description
length of hospital stay
Timepoint
time of discharge from hospital
Method of measurement
Based on patients records

Intervention groups

1

Description
intervention in control group: receive 5 cc of sterile water in 50 cc normal saline
Category
Treatment - Drugs

2

Description
intervention in case group: infusion of 2.5 grams of Mgso4 in 50 cc normal saline in 20 minutes
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Elham Pishbin
Street address
Imam Reza squer , Ibne sinastreet
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chanceller for research of Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Mashhad - Daneshgah Ave. - Mashhad University of Medical Sciences-Vice Chanceller for research
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vcresraech@mums.ac.ir
Web page address
https://v-research.mums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chanceller for research of Mashhad 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
Mashhad University of Medical Sciences - Imam Reza hospital
Full name of responsible person
Elnaz Vafadar Moradi
Position
Emergency medicine resident
Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Imam Reza Square- Ibne e Sina street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences - Imam Reza hospital

Full name of responsible person

Elham Pishbin

Position

Assistant Professor of Emergency medicine

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Latest degree

Medical doctor

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Emergency Medicine

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elnaz.vafadar@gmail.com

Web page address

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data related to the main outcomes and the basic characteristics of patients

When the data will become available and for how long

6 months after publication of the manuscript of this study

To whom data/document is available

academic researchers

Under which criteria data/document could be used

for clinical studies

From where data/document is obtainable

Elham Pishbin Tel: 00985138525312 pishbine@mums.ac.ir

What processes are involved for a request to access data/document

The request should be sent to the main investigator (Elham Pishbin) whose address is mentioned above and also a copy to the vice chancellor for research in Mashhad university of medical scinces

Comments