# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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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Mashhad
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+98 51 3852 5312
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pishbine@mums.ac.ir

## 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
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Mashhad - Daneshgah Ave. - Mashhad University of Medical Sciences-Vice Chanceller for research
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**Phone**
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**Email**
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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## Person responsible for scientific inquiries

**Contact**

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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**

Emergency Medicine

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## Person responsible for updating data

**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

**Street address**

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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**

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**