

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 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 admission

Timepoint

any time during first 12 hours of admission

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 , lbne sinastreet

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۱۳۷۹۱۳۳۱۶

Phone

+98 51 3852 5312

Email

pishbine@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor 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 Chancellor for research

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

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 Chancellor 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
Street address
Imam Reza Square- Ibne e Sina street
City
Masshad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3852 5312
Fax
Email
elnaz.vafadar@gmail.com
Web page address

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
Emergency Medicine
Street address
Imam Reza squer , Ibn e Sina street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3852 5312
Fax
+98 51 3852 5312
Email
pishbine@mums.ac.ir
Web page address
<http://www.mums.ac.ir>

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
Imam Reza Square- Ibne e Sina street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3852 5312
Fax
Email
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 sciences

Comments