Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of inhaled magnesium sulfate on the duration of hospitalization and spirometry indicators in patients with chronic obstructive pulmonary disease

Protocol summary

Study aim

Determination of the effect of inhaled magnesium sulfate on the length of hospital stay and spirometric indices during exacerbations in patients with chronic obstructive pulmonary disease (COPD).

Design

This is a phase 2 randomized clinical trial with parallel groups and single-blind design (patients blinded), conducted on 174 patients with COPD. Participants are randomly assigned to the intervention and control groups using the rand function in Excel.

Settings and conduct

This clinical trial will be conducted on 348 patients aged 30 to 70 years with acute exacerbation of COPD at Shahid Beheshti Hospital, Kashan University of Medical Sciences. Patients are randomly assigned using block randomization to receive either standard treatment or standard treatment plus inhaled magnesium sulfate, and clinical and paraclinical outcomes will be assessed according to the study protocol.

Participants/Inclusion and exclusion criteria

Participants: Individuals with a previous diagnosis of COPD who have been admitted to the hospital due to an acute exacerbation, or whose COPD has been diagnosed through spirometry and have an FEV1 ≤ 80% or FEV1/FVC < 70%. Intervention: Individuals with a previous diagnosis of COPD who have been admitted to the hospital due to an acute exacerbation and have had their COPD diagnosed through spirometry. In addition to the standard pharmacological treatment regimen for acute exacerbations, this group will receive inhaled magnesium sulfate.

Intervention groups

The control group receives only the standard treatment for acute COPD exacerbation. The intervention group, in addition to the standard treatment, also receives inhaled magnesium sulfate via nebulizer

Main outcome variables

Length of hospital stay; Interval to rehospitalization (up to 6 months); Improvement in FEV1 based on spirometry after 5 days; CRP level (quantitative, after 5 days)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250528065953N1**
Registration date: **2025-07-21, 1404/04/30**
Registration timing: **prospective**

Last update: **2025-07-21, 1404/04/30**
Update count: **0**

Registration date

2025-07-21, 1404/04/30

Registrant information

Name

Amir Dasdar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-01, 1404/05/10

Expected recruitment end date

2025-09-01, 1404/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of inhaled magnesium sulfate on the duration of hospitalization and spirometry indicators in patients with chronic obstructive pulmonary disease

Public title

Inhaled magnesium sulfate in COPD (Chronic Obstructive Pulmonary Diseases)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with a history of COPD who have been hospitalized due to acute exacerbations Individuals who have been diagnosed with COPD through spirometry Individuals who have an FEV1 of 80% or lower and/or an FEV1/FVC ratio of less than 70%.

Exclusion criteria:

Pneumonia Malignancy CHF (Congestive Heart Failure) Astham Hospitalization for a reason other than chronic obstructive pulmonary disease (COPD) exacerbation.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **384**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization was used, with the individual as the unit of randomization. To randomly assign participants to the study groups, a block randomization method with blocks of four was applied. The blocks included the following sequences: (AABB), (BBAA), (BABA), (ABAB), (ABBA), and (BAAB), where "A" represents the treatment group and "B" represents the placebo group. The selection of blocks was performed using the RandInt function in Microsoft Excel.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since an objective measurement tool is used in the study, the risk of bias is minimized. Additionally, a placebo will not be used, as all patients receive standard bronchodilator therapy via nebulizer during treatment. Therefore, only the clinical data analyst and outcome assessor will be blinded to the treatment allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Faculty of Medicine & Faculty of Dentistry – Kashan University of Medi

Street address

Pezeshk Blvd. Qotb Blvd.

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2025-05-11, 1404/02/21

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1404.030

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

Length of Hospital stay

Timepoint

Once, at the time of the patient's discharge.

Method of measurement

Patient medical records

2

Description

FEV1/FVC

Timepoint

Baseline and after 5 days

Method of measurement

with Spirometry

Secondary outcomes

1

Description
Admission Interval
Timepoint
Up to 6 month after the primary discharge
Method of measurement
Based on the patient's medical record

2

Description
GOLD
Timepoint
On each admission time
Method of measurement
Based on Spirometry and GOLD criteria

3

Description
FEV1
Timepoint
Baseline (from the admission) and 5 days after admission
Method of measurement
Spirometry

Intervention groups

1

Description
Intervention group: The other 118 patients, in addition to receiving standard treatment, will be administered ready-to-use vials of inhaled magnesium sulfate via nebulizer at a dose of 1 gram every 12 hours for five days.
Category
Treatment - Drugs

2

Description
Control group: 118 patients will receive standard treatment for acute exacerbation of COPD, which includes supplemental oxygen (if oxygen saturation is below 88% in patients without a cardiac history), bronchodilators (salbutamol administered via nebulizer or MDI depending on the patient's condition), systemic corticosteroids at the standard COPD dose (35 to 40 mg of prednisolone or its equivalent), and broad-spectrum antibiotics for five days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid beheshti hospital, Kashan
Full name of responsible person
Yazdan Jafari
Street address
Pezeshk Blvd., Qotb Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Amir Dasdar
Position
Internal medicine Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
No - There is not 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
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 will be fully accessible only after ensuring the anonymity of the participants.
When the data will become available and for how long
6 months after publication
To whom data/document is available
Every individual who send his/her request to corresponding author and corresponding author confirm his/her access
Under which criteria data/document could be used
the purpose is to ensure the proper conduct of the study and to use the data for more accurate future research."
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
Send email to corresponding author - assessment of the request and confirm/reject the access
Comments