Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of prescribing aminophylline on the recovery of patients with acute COPD attack requiring noninvasive mechanical ventilation and investigating its effect on increasing the efficiency of the respiratory system

Protocol summary

Study aim
The aim of this study is to evaluate the effect of aminophylline on blood gases, respiratory symptoms, and hospitalization outcomes in patients with COPD.

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 1 on 70 patients.

Settings and conduct
In Isfahan province, patients are randomly assigned to the intervention (aminophylline) and control (standard treatment) groups. Allocation is performed by an independent person from the treatment team. The study is designed as double-blinded, meaning both patients and assessors are unaware of the treatment type. This is achieved using a placebo with a similar appearance and administration method, along with drug coding. All patients will be continuously monitored for blood gases, clinical symptoms, and pulmonary function.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 20-80 with acute COPD exacerbation. Exclusion criteria: Cardiovascular issues, pneumonia, lung malignancy, decreased consciousness, facial/chest deformities, asthma, advanced malignancy.

Intervention groups
Intervention group: Patients receive aminophylline (250 mg loading dose, 30 mg/hour maintenance) per standard protocol. Control group: Patients receive standard COPD treatment without aminophylline. Both groups are monitored for blood gases, symptoms, and lung function.

Main outcome variables
This study examines the effect of aminophylline on pulmonary function (FEV1, FVC) in patients with acute COPD exacerbation. It analyzes potential improvements in the intervention group compared to the control to assess the intervention’s effectiveness.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241118063763N1**
Registration date: **2025-03-30, 1404/01/10**
Registration timing: **prospective**

Last update: **2025-03-30, 1404/01/10**
Update count: **0**

Registration date
2025-03-30, 1404/01/10

Registrant information

Name
Noora Behzadian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-01, 1404/04/10

Expected recruitment end date
2026-02-20, 1404/12/01

Actual recruitment start date
2025-07-01, 1404/04/10

Actual recruitment end date
2026-02-20, 1404/12/01

Trial completion date

2026-04-09, 1405/01/20

Scientific title
The effect of prescribing aminophylline on the recovery of patients with acute COPD attack requiring noninvasive mechanical ventilation and investigating its effect on increasing the efficiency of the respiratory system

Public title
The effect of prescribing aminophylline on the recovery of patients with acute COPD attack requiring noninvasive mechanical ventilation and investigating its effect on increasing the efficiency of the respiratory system

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20 and 80 years. Have an acute attack of COPD. Require NIV treatment. No trauma or facial deformity. No severe decreased level of consciousness. No copious pulmonary secretions. No high risk of aspiration. No cardiorespiratory arrest.

Exclusion criteria:
No cardiovascular problems (heart failure, ischemia, arrhythmia, unstable hemodynamics resistant to treatment). No allergy to theophylline or aminophylline. No stomach ulcer. No pneumonia diagnosed in the chest X-ray. No lung malignancy. No decreased level of consciousness. No face or chest deformity. No asthma. No advanced malignancy of any type. No neuromuscular diseases or chest disorders. No pneumothorax. Not pregnant or breastfeeding. No persistent and frequent vomiting. Able to tolerate NIV. No history of theophylline use.

Age
From **42 years** old to **90 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **70**
Actual sample size reached: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 70 eligible patients from those who visited Al-Zahra Hospital were randomly selected. For the random allocation of patients into the intervention and control groups, (specify the method, e.g., random number table, randomization software, or other methods such as block randomization or allocation based on odd and even numbers) was used. This process was conducted by an independent individual, separate from the treatment team, to ensure impartiality. After the initial assessments and necessary tests, the required medications were prescribed for each patient according to the study protocol.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients did not know the type of study and only took the drugs to treat the disease. Also, the researcher and clinical caregivers were unaware of the final outcome

Placebo
Not used

Assignment
Parallel

Other design features
It should be noted that this study has been conducted for the first time in Iran and is unique in its own way.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Second Floor, Building No. 4, Headquarters, University Campus, Hezar Jerib, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
73461-81746

Approval date
2024-11-13, 1403/08/23

Ethics committee reference number
IR.MUI.MED.REC.1403.331

Health conditions studied

1

Description of health condition studied
chronic obstructive pulmonary disease

ICD-10 code
J96.1

ICD-10 code description
Chronic respiratory failure

Primary outcomes

1

Description
Examination of lung volume in the control and

intervention groups

Timepoint

The effect of aminophylline after 3 days in the intervention group

Method of measurement

Examination of lung volumes through spirometry

2

Description

Examination of blood gases in two intervention and control groups

Timepoint

Investigating the effect of aminophylline on blood gases in the intervention group after 3 days

Method of measurement

Measurement by taking blood from the patient

3

Description

Examination of shortness of breath in two intervention and control groups

Timepoint

After the injection of the drug up to three days after the injection

Method of measurement

Borg questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aminophylline is administered at a loading dose of 250 mg and a maintenance dose of 30 mg/hour.

Category

Treatment - Drugs

2

Description

Control group: Received standard treatment for an acute COPD attack without aminophylline administration.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

AL Zahra Hospital

Full name of responsible person

Mrs. Dr. Somieh Sadeghi Haddadzwarah

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Plot 70, Phase 3, Ilham Western St., Kianpars, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Gholamreza Asgari

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Noora Behzadian

Position

Resident

Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
We are in the process of selecting a journal for submission.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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