

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effect of aminophylline in patients with AECOPD who are candidate for Noninvasive mechanical ventilation

Protocol summary

Study aim

Effect of aminophylline in patients with AECOPD who are candidate for Noninvasive mechanical ventilation

Design

parallel group, double blind, randomised controlled clinical trial

Settings and conduct

The study population consists of COPD patients with acute exacerbation who are admitted in Alzahra hospital emergency department in 2019, 2020 and meet the inclusion criteria. The patients are divided into case and control groups by means of random numbers table. Control group are treated with inhaled short-acting B2 agonist, inhaled short-acting anticholinergic, systemic corticosteroid and NIV. Intervention group are treated with addition of loading and maintenance dose of IV aminophylline to the previously mentioned drugs. Dosage of aminophylline is calculated based on pharmacokinetic formulas individually to achieve serum level of 10 mg/ml. In order to double-blind the sampling, normal saline is used in control group and health care provider has no role in patients outcome assessment. Dyspnea improvement, number of admission days, intubation, ICU admission, aminophylline side effects occurrence and blood gas and spirometry parameters are compared between groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with AECOPD who are candidate for Noninvasive mechanical ventilation

Exclusion criteria: allergy to theophylline or aminophylline; recent use of theophylline; cardiovascular diseases; pneumonia and pneumothorax

Intervention groups

control group: prescription of inhaled fast acting B2-agonist, inhaled fast acting anticholinergic and systemic corticosteroid and NIV intervention group: prescription of inhaled fast acting B2-agonist, inhaled fast acting anticholinergic and systemic corticosteroid, loading and maintenance dose of IV aminophylline and NIV

Main outcome variables

blood gas parameters; dyspnea score; lung volumes (FEV1, FVC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200204046374N1**

Registration date: **2020-04-13, 1399/01/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-13, 1399/01/25**

Update count: **0**

Registration date

2020-04-13, 1399/01/25

Registrant information

Name

Somayeh Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3261 6331

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of aminophylline in patients with AECOPD who are candidate for Noninvasive mechanical ventilation

Public title
Effect of aminophylline in patients with AECOPD candidates for non invasive ventilation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patients with AECOPD who are candidate for Noninvasive mechanical ventilation no contraindication of NIV
Exclusion criteria:
 cardiovascular diseases allergy to theophylline or aminophylline gastric ulcer pneumonia according to chest x-ray malignancy facial or chest deformity asthma pregnancy and lactation pneumothorax recent use of theophylline

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is performed by means of random numbers table.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the patients, instead of aminophyllin, normal saline is prescribed in control group.
Furthermore, the investigator of the outcome does not attend the patients room during drugs prescription.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Isfahan medical university Committee for Ethics in Biomedical Research
Street address
 Hezar jarib St.
City
 Isfahan
Province
 Isfahan
Postal code
 8174673461
Approval date
 2019-08-04, 1398/05/13
Ethics committee reference number
 IR.MUI.MED.REC.1398.237

Health conditions studied

1

Description of health condition studied
 acute exacerbation of COPD requiring noninvasive mechanical ventilation
ICD-10 code
 J44.1
ICD-10 code description
 Chronic obstructive pulmonary disease with acute exacerbation, unspecified

Primary outcomes

1

Description
 blood gas parameters
Timepoint
 2 hours after initiation of the treatment and then daily
Method of measurement
 ABG testing

2

Description
 dyspnea score
Timepoint
 daily
Method of measurement
 Borg scale

3

Description
 Lung volumes(FEV1 , FVC)
Timepoint
 4-6 hours after initiation of the treatment and then on the third day of admission
Method of measurement
 post bronchodilation spirometry

Secondary outcomes

1

Description

aminophylline side effects

Timepoint

daily and every 6 hours

Method of measurement

history and physical examination

2

Description

number of admission days

Timepoint

discharge date

Method of measurement

count of admission days

Intervention groups

1

Description

Control group: prescription of fast acting inhaled B2-agonist, fast acting inhaled anticholinergic and systemic corticosteroid and NIV

Category

Treatment - Drugs

2

Description

Intervention group: prescription of fast acting inhaled B2-agonist, fast acting inhaled anticholinergic and systemic corticosteroid, loading and maintenance dose of IV aminophylline and NIV

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr. Somayeh Sadeghi

Street address

Soffe Blvd.

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8174675731

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghighi Monfared

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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

Dr. Somayeh Sadeghi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Demographic data and the result of statistical analysis of the clinical trial

When the data will become available and for how long

2 year later

To whom data/document is available

Researchers

Under which criteria data/document could be used

after publication of the article

From where data/document is obtainable

sending Email to the researchers

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

Sending the request via the email

Comments