Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 hosptial 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-bling 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)

Phone
+98 31 3261 6331

Email address
s.sadeghi@med.mui.ac.ir

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 pnuemonia 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

Isfehan

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.
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Shaghayegh Haghjoy Monfared
Street address
Hezar jarib St.
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Phone
+98 31 3668 5149
Email
research@mui.ac.ir
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
Street address
Soffeh Blvd.
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone

+98 31 3620 2020

Email

s.sadeghi117917@gmail.com

Person responsible for scientific 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

Street address

Soffeh Blvd.

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

s.sadeghi117917@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mohammadsaeid Khaksar

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Soffeh Blvd.

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

msaeid.khaksar@yahoo.com

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