

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The Effect of Nebulized Ketamine in Treatment of Patients with Chronic Obstructive Pulmonary Disease Exacerbation (COPD exacerbation)

Protocol summary

Study aim

Evaluating the effect of nebulized Ketamine in treatment of patients with chronic obstructive pulmonary disease exacerbation

Design

Two arm parallel group randomised clinical trial, double-blind, phase 3 on 80 patients (40 people in each group)

Settings and conduct

80 patients with COPD who referred to the emergency room of Shahid Rahmonun and Shahid Sadoughi hospitals, Yazd, Iran with moderate or severe exacerbation of symptoms and were divided into two intervention and placebo groups using a random number table. The evaluating doctor and the patient are blinded about the received medicine, and only the nurse knows that.

Participants/Inclusion and exclusion criteria

Exclusion criteria: under 16 and over 60 years old heart, kidney, liver failure Oral fever above 38.3° C Low or high blood pressure Decreased level of consciousness and other brain disorders Suspicion of other respiratory diseases Inability to use peak expiratory flow meter Severe respiratory distress requiring intubation or NIV Pregnant women Known allergy to ketamine

Intervention groups

Control Group receives the main treatment with a standard dose (nebulizer 2.5 mg of albuterol and 5 mg of Atrovent and intravenous injection of methylprednisolone 1 mg per weight and oxygen with Venturi mask) along with nebulizer placebo (saline). Intervention Group: In addition to standard treatment, they receive ketamine nebulizer with a dose of 0.5 mg per weight and a maximum of 25 mg. After 20 minutes, if the symptoms do not improve, the above method is repeated again.

Main outcome variables

Age, gender, treatment group, PEFR, respiratory rate, heart rate, dyspnea severity score, Sa O₂, VBG, need for intubation or NIV, need for hospitalization, level of satisfaction of the attending physician, rate of

complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200809048341N3**

Registration date: **2024-01-20, 1402/10/30**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-20, 1402/10/30**

Update count: **0**

Registration date

2024-01-20, 1402/10/30

Registrant information

Name

Soheila Azimi Aabarghouei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Nebulized Ketamine in Treatment of Patients with Chronic Obstructive Pulmonary Disease Exacerbation (COPD exacerbation)

Public title

The Effect of Ketamine in Treatment of COPD exacerbation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 16 to 60 years with moderate to severe COPD who refer to the emergency room of Shahid Rahmonun and Shahid Sadoughi hospitals and do not meet the exclusion criteria.

Exclusion criteria:

Patients under 16 and over 60 years old Heart, kidney, liver failure Patients with heart diseases such as arrhythmia, ischemic heart diseases, etc. Oral fever above 38.3 degrees Celsius Low blood pressure (diastolic blood pressure less than 90 mm Hg) or high blood pressure (systolic blood pressure more than 180 mm Hg) glaucoma Decreased level of consciousness, brain tumor, suspicion of increased intracranial pressure (ICP) for any reason, psychosis, history of seizures and other brain disorders... Suspicion of other respiratory diseases such as pneumonia, pneumothorax, pulmonary embolism, pulmonary edema, etc. Inability to use peak expiratory flow meter Severe respiratory distress requiring intubation or NIV Pregnancy Known allergy to ketamine.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

From all patients with COPD who refer to the emergency department of Shahid Rahmonun and Shahid Sadouqi hospitals with moderate or severe exacerbation of symptoms, according to the entry and exit criteria, 80 people are included in the study and are divided into two intervention and placebo groups using a random number table. Tables of random numbers are prepared by computers that arrange numbers randomly, which are divided into blocks of five digits to facilitate its use. In this method, the community members are numbered from 1 to 80, then a row and a column of the table are randomly selected. The intersection point of the selected row and column is the starting point of sampling. (choose the point by closing eyes, placing finger or pen tip on the

table). and only pays attention to and selects the smaller numbers. From this point, a plus or a cross is drawn. All the numbers that are added or crossed over are selected as members of the sample. This process continues until the required sample (40 cases) is selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding was that a sheet with A and B written on it was placed in the envelopes. The evaluating doctor held these closed envelopes in front of the patient and asked them to choose one and without looking inside the envelope, he gave it to the relevant nurse, so that according to whether it was A or B inside the envelope, he would prescribe the medicine for the patient. The evaluating doctor did not know the type of medicine received by the patient. With this method, the patient did not know the type of treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Medicine _ Shahid Sadoughi University of Medical Sciences

Street address

Central building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd

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Approval date

2020-05-11, 1399/02/22

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.018

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease Exacerbation (COPD exacerbation)

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with (acute) exacerbation

Primary outcomes

1

Description

Peak expiratory flow rate (PEFR) improvement

Timepoint

Upon arrival, 60 minutes later, 4 hours later

Method of measurement

By the peak flow monitor, after taking a deep breath, the patient blows into the device 3 times with maximum speed and power, and the best one is selected for study.

2

Description

Increase Arterial O₂ Saturation(SaO₂)

Timepoint

Upon arrival, 20, 40, 60 ,90 , 120 minutes later, 4 hours later

Method of measurement

By pulse oximeter

3

Description

Decrease pulse rate and respiratory rate

Timepoint

Upon arrival, 20, 40, 60 ,90 , 120 minutes later, 4 hours later

Method of measurement

By monitoring device

4

Description

Improvement of dyspnea severity score

Timepoint

Upon arrival, 20, 40, 60 ,90 , 120 minutes later, 4 hours later

Method of measurement

Based on the modified Borg dyspnea scale, the patient scored the severity of her/his dyspnea from 0 to 10

Secondary outcomes

1

Description

The need for hospitalization

Timepoint

On arrival, 60 minutes and 4 hours later

Method of measurement

Based on the clinical symptoms and severity of the patient's dyspnea

2

Description

The need for a second dose of the drug

Timepoint

On arrival, 60 minutes and 4 hours later

Method of measurement

Based on the clinical symptoms and severity of the patient's dyspnea

3

Description

The extent of the need to start rescue medication

Timepoint

On arrival, 60 minutes and 4 hours later

Method of measurement

Based on the clinical symptoms and severity of the patient's dyspnea

Intervention groups

1

Description

Intervention Group: In addition to standard treatment, they receive ketamine nebulizer with a dose of 0.5 mg per weight and a maximum of 25 mg. After 20 minutes, if the symptoms do not improve, the above method is repeated again.

Category

Treatment - Drugs

2

Description

ontrol Group: receives the main treatment with a standard dose (nebulizer 2.5 mg of albuterol and 5 mg of Atrovent and intravenous injection of methylprednisolone 1 mg per weight and oxygen with Venturi mask) along with nebulizer placebo (saline).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahnamoun hospital

Full name of responsible person

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Title and more details about the data/document

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

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

Comments