# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

**City**
Yazd

**Province**
Yazd

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89416978477

**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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### 2

**Recruitment center**

**Name of recruitment center**
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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
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**
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Yazd University of Medical Sciences
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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**