

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Evaluation of the effectiveness of medroxyprogesterone on blood gases and short term hospital outcomes in patients with Chronic Obstructive Pulmonary Disease (COPD) exacerbation who received Non Invasive Ventilation (NIV)

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of Medroxyprogesteron compared to placebo on blood gases and short term hospital outcomes (dyspnea, hospitalization days, ICU admission, intubation, O2 saturation and NIV hours/day usage) in patients with Chronic Obstructive Pulmonary Disease (COPD) exacerbation who received Non Invasive Ventilation (NIV)

##### Design

Two arm parallel group randomised trial, double blinded, phase3, design of 75 patients, randomised base on permuted block randomization

##### Settings and conduct

This study is done in Al-Zahra and Khorshid hospital at Isfahan, Chronic Obstructive Pulmonary Disease (COPD) exacerbation patients who are randomisation with Random Allocation software. Intervention group recieve medroxy progesteron and control group recieve placebo. Both groups also recieve standard cares and Non Invasive Ventilation (NIV)

##### Participants/Inclusion and exclusion criteria

Inclusion criteria:Chronic Obstructive Pulmonary Disease (COPD) exacerbation patients who has one of this criteria (dyspnea, increased sputum volume, and a change in the nature of sputum) COPD exacerbation patient who needs Non Invasive Ventilation (NIV) Age between 30-80  
Exclusion criteria: Requiring mechanical ventilation by the time of admission Having a current or history of thromboembolic diseases History of cerebrovascular disease, history of myocardial infarction (MI) and stroke Unexplained vaginal bleeding History of breast cancer, or any estrogen- or progesterone-dependent tumor Decreased level of consciousness Deformity or trauma in face

##### Intervention groups

Intervention group received tablets of progesterone 15

mg, every 6 hours for 5 days and control received placebo tablets with similar shape to progesterone tablets.

##### Main outcome variables

Atrial Blood Gases(ABG), hospital short outcome (dyspnea,hospitalization days,ICU admission,intubation,O2 saturation ,NIV hours/day usage)

#### General information

##### Reason for update

##### Acronym

Chronic Obstructive Pulmonary Disease(COPD) بیماری انسدادی مزمن ریوی یا تهویه غیر تهاجمی یا / (NIV)

##### IRCT registration information

IRCT registration number: **IRCT20211031052922N1**  
Registration date: **2021-12-01, 1400/09/10**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

##### Registration date

2021-12-01, 1400/09/10

##### Registrant information

##### Name

Mina Nickpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4404 6694

##### Email address

drminanickpour@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**  
**Funding source**

**Expected recruitment start date**  
2021-08-23, 1400/06/01

**Expected recruitment end date**  
2022-04-21, 1401/02/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effectiveness of medroxyprogesterone on blood gases and short term hospital outcomes in patients with Chronic Obstructive Pulmonary Disease (COPD) exacerbation who received Non Invasive Ventilation (NIV)

**Public title**  
Effect of Medroxy progesteron in Chronic Obstructive Pulmonary Disease (COPD) exacerbation

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Chronic Obstructive Pulmonary Disease (COPD) exacerbation patients who has one of this criteria(dyspnea, increased sputum volume, and a change in the nature of sputum) COPD exacerbation patient who needs Non Invasive Ventilation (NIV) Age between 30-80 Signing the written informed consent

**Exclusion criteria:**  
Requiring mechanical ventilation by the time of admission Having a current or history of thromboembolic diseases like Pulmonary Thrombosis Embolie (PTE), active thrombophelebitis, Deep Vein Thrombosis (DVT) History of cerebrovascular disease, history of myocardial infarction (MI) and stroke Unexplained vaginal bleeding Hepatic diseases Pregnancy History of breast cancer or any estrogen or progesterone dependent tumors History of allergy to hormonal drugs containing progesterone Stable and frequent vomiting Decreased level of consciousness Deformity or trauma in face

**Age**  
From **30 years** old to **80 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients were recruited based on the mentioned criteria

and 70 patients are selected.They are randomly divided into two groups based on permuted block randomization by using Random Allocation software that each group(case and control)contain of 35 participant.For assurance of participant are divided equally to case and control in consecutive interval,we use 10 blocked randomization that each of them contain 7 participant.Odd blocks are interventional group and even blocks are control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study participants and doctors are blind.participant after signing informed consent,accept that may recieve drug or placebo.Doctors dont know which patient may recieve medroxy progesteron or placebo.Doctors after initial visit of COPD exacerbation patients who need Non Invasive Ventilation(NIV),report the patients to study supervisor(pulmonary fellowship).Study supervisor is checking inclusion and exclusion criteria and recieved informed consent.After randomazation by study supervisor ,drugs or placebo are taken to nurse of patients (who are blind)for daily prescription.Also nurse dont know that the patient recieve placebo or drug.Study forms are completed by doctors daily.After 5th days,supervisor collect forms and drug or placebo prescription discontinue.

**Placebo**

Used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Isfahan University of Medical science

**Street address**

Isfahan Medical Univesity , Hezarjarib Ave, Esfahan

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2020-11-20, 1399/08/30

**Ethics committee reference number**

IR.MUI.MED.REC.1399.654

**Health conditions studied**

## 1

### **Description of health condition studied**

Chronic Obstructive Pulmonary Disease(COPD)  
Exacerbation

### **ICD-10 code**

J44.1

### **ICD-10 code description**

Chronic obstructive pulmonary disease with acute exacerbation, unspecified

## **Primary outcomes**

### 1

#### **Description**

ICU admission

#### **Timepoint**

Daye1;3;5

#### **Method of measurement**

doctors reports

### 2

#### **Description**

Intubation

#### **Timepoint**

Days1,3,5

#### **Method of measurement**

Doctors reports

### 3

#### **Description**

venous blood gase

#### **Timepoint**

Days1,3,5

#### **Method of measurement**

ABG analysor

### 4

#### **Description**

O2saturation

#### **Timepoint**

Days1,3,5

#### **Method of measurement**

Pulse oximetry

## **Secondary outcomes**

### 1

#### **Description**

Hospitalization days

#### **Timepoint**

In day 5 and days of discharge

#### **Method of measurement**

Days of hospitalization

### 2

#### **Description**

Dyspnea score

#### **Timepoint**

Days 1,3,5

#### **Method of measurement**

Borg scale

### 3

#### **Description**

Non Invasive Ventilation(NIV) hours/day usage

#### **Timepoint**

Days 1,3,5

#### **Method of measurement**

Based on doctors reports

## **Intervention groups**

### 1

#### **Description**

Intervention group: prescription medroxy pogesteron acetate 15mg per 6 hour until 5days to COPD (Chronic Obstructive Pulmonary Disease)exacerbation patients who needs Non InvasiveVentilation(NIV) .Medroxy progesteron tablets 5 mg are produced by Aboreyhan company.We prescript 3tablets of medroxy progesteron 5mg(15mg) every 6 hour.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: prescription placebo that similar to Medroxy progesteron per 6 hour to COPD exacerbation patients(every 6hour precript 3 tablet of placebo).We will produce placebo with help of faculty of pharmacy of Isfahan medical university.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Al-Zahra hospital

##### **Full name of responsible person**

Mina Nickpour

##### **Street address**

Al-Zahra hospital, Hakim Nezami Ave, Esfahan

##### **City**

Esfahan

##### **Province**

Isfahan

##### **Postal code**

8174675731

##### **Phone**

+98 31 3263 8279

##### **Fax**

##### **Email**

## 2

### Recruitment center

**Name of recruitment center**

Khorshid hospital

**Full name of responsible person**

Mina Nickpour

**Street address**

Khorshid hospital, Ostandari Ave, Esfahan

**City**

Esfahan

**Province**

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**Email**

minanickpour@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr Shaghayegh Haghjoo

**Street address**

University of Esfahan, Hezar jarib Ave, Medicine  
Research Department

**City**

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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**

Mina Nickpour

**Position**

Pulmonology fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pulmonology

**Street address**

Khorshid hospital, Ostandari Ave, Esfahan

**City**

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**Postal code**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mina Nickpour

**Position**

Pulmonology fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mina Nickpour

**Position**

Pulmonology Fellowship

**Latest degree**

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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**

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**

We decide to share our questionnaire forms (after unidentifiable) and SPSS files of primary and secondary variables and data analysis of our study by other researchers

**When the data will become available and for how long**

6 month after article is published

**To whom data/document is available**

Researcher in medical and pharmaceutical field that work in university or pharmacy company

**Under which criteria data/document could be used**

After we study their study proposal, usage of our data will be possible. Analysis of our data according to their study will be possible. If usage of our data help them to result in an article, we expect our name mention as colleague

**From where data/document is obtainable**

Email to me minanickpour@yahoo.com

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

First we must study their research proposal, if our data help them, immediately we give our data and SPSS files and other files if needed

**Comments**