Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Nov 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

بیماری انسدادی مزمن ریوی یاChronic Obstructive Pulmonary Disease(COPD) /تهویه غیر تهاجمی یاNon Invasive Ventilation (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 supervisior(pulmonary fellowship).Study supervisior 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,supervisior 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
Isfehan

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 oximetery

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
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2

Recruitment center
Name of recruitment center
Khorshid hospital
Full name of responsible person
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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 Haghjoo
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University of Esfahan, Hezar jarib Ave, Medicine Research Department
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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
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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 questionare 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
Reshearcher 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 ourdata according to their study will be possible.if usage 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 datas and SPSS files and other files if needed
Comments