Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of Effectiveness of Dexamethazone versus Hydrocortisone in Reducing Hospital Length, Oxidative Stress Factors and Inflammatory Mediators in Chronic Obstructive Pulmonary Disease (COPD) Exacerbation Patients.

Protocol summary

Study aim

Comparing the effectiveness of hydrocortisone and dexamethasone on reducing clinical symptoms,laboratory data in patients with exacerbation of chronic obstructive pulmonary disease hospitalized in the internist department.

Design

A clinical trial with two intervention groups, double-blind, randomized, on 70 patients with exacerbation of chronic obstructive pulmonary disease who were randomly divided into two groups of 35 by computer random generation.

Settings and conduct

Study place:Imam Sajjad Hospital,Yasuj. For patients with admission conditions,clinical and laboratory variables'll be measured and recorded, and standard treatment'll begin for all of them. After randomization, group 1 patients are given 8 mg of single-dose intravenous(IV) dexamethasone daily, group 2 are given 200 mg of IV hydrocortisone daily in 4 divided doses. Variables will be measured and recorded daily till patients get condition for discharge. Profiles and clinical examinations of patients as well as tests'll be performed by people who are blind to the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients hospitalized due to exacerbations of chronic obstructive pulmonary disease. Exclusion criteria: asthma, systemic corticosteroids use within the past month, recent myocardial infarction, acute irreversible heart failure, diagnosis of lobar pneumonia on Xray or lung CT scan

Intervention groups

group1:the patients recieve 8mg IV dexametasone daily, In addition to standard treatment group2:the patients recieve 200mg IV hydrocortisone daily, In addition to standard treatment

Main outcome variables

General condition, Sputum level and density,Cough,Shortness of breath,Peak Expiratory Flow,Peripheral White Blood Cell Count,Acute Phase Reactive Protein,Malondialdehyde,Edema,Peripheral Blood Potassium,Systemic Blood Pressure,Sleep quality,Hospitalization Count,Arterial Blood Oxygen Saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200818048447N1**
Registration date: **2021-11-10, 1400/08/19**
Registration timing: **retrospective**

Last update: **2021-11-10, 1400/08/19**
Update count: **0**

Registration date

2021-11-10, 1400/08/19

Registrant information

Name

Śeyed Ahad Hoseyni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-03-05, 1399/12/15
Expected recruitment end date
2021-07-03, 1400/04/12
Actual recruitment start date
2021-03-05, 1399/12/15
Actual recruitment end date
2021-07-09, 1400/04/18
Trial completion date
2021-07-11, 1400/04/20

Scientific title
Evaluation of Effectiveness of Dexamethazone versus Hydrocortisone in Reducing Hospital Length, Oxidative Stress Factors and Inflammatory Mediators in Chronic Obstructive Pulmonary Disease (COPD) Exacerbation Patients.

Public title
Evaluation of the Effectiveness of Hydrocortisone and Dexamethasone in the Management of Patients with Chronic Obstructive Pulmonary Disease Exacerbation.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 40 years Confirmed history (FEV1 / FVC <70%) of COPD or typical history (prolonged smoking and chronic sputum and cough) Exacerbations of the disease include increased cough, sputum, and shortness of breath
Exclusion criteria:
History of Asthma or Atopy Consumption Systemic Corticosteroids within the Last Month before Hospitalization Recent Myocardial Infarction Not Compensated Acute Heart Failure Diagnosis of Lobar Pneumonia on X-ray or CT scan of the Lungs
Age
From **35 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The 70 patients in the study are randomly divided into two groups of 35 with a one-to-one ratio by complete random generation method. For this purpose, first the list of patients' names is prepared and numbered from 1 to 70, then patients with odd numbers will be assigned to group one and patients with even numbers will be assigned to group two.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients are explained that glucocorticoid drugs are standard treatment and there are no evidences to show one of them to be more effective than other in current condition. In this way, although patients do not know the name of their glucocorticoid drug, they will be aware of the general class of drugs and their side effects. Specifications and examinations will be recorded by a person who is blind to the groups and tests will be recorded by a person who is blind to the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
Motahary Av. University of Medical Sciences
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Approval date
2021-03-05, 1399/12/15
Ethics committee reference number
IR.YUMS.REC.1399.198

Health conditions studied

1

Description of health condition studied
Chronic Obstructive Pulmonary Disease
ICD-10 code
J44.9
ICD-10 code description
Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description
Dyspnea
Timepoint
Daily till discharge
Method of measurement

Questionnaire. Patients score from 1 to 10 depending on the severity of dyspnea

2

Description
Sputum volume
Timepoint
Daily
Method of measurement
Questionnaire. Patients score from 1 to 10 depending on the sputum volume

3

Description
Couph
Timepoint
Daily
Method of measurement
Questionnaire. Patients score from 1 to 10 depending on the severity of couph

4

Description
Arterial Oxygen Saturation
Timepoint
Daily
Method of measurement
Pulse Oxymeter Device

Secondary outcomes

1

Description
Duration of Hospitalization
Timepoint
Time of Discharge
Method of measurement
Counting the days of hospitalization

2

Description
Sleep quality
Timepoint
Daily
Method of measurement
Patients score from 1 to 10 depending on their sleep quality

3

Description
Peripheral white blood cell count
Timepoint
Day of hospitalization and day of discharge
Method of measurement
Auto-analyzer device in the form of thousand in microliters

4

Description
Peak Expiratory Flow
Timepoint
Daily
Method of measurement
Peakflowmeter device

5

Description
Edema
Timepoint
Daily
Method of measurement
Physician evaluation. Scoring from 1 to 4

6

Description
Peripheral Blood Potassium
Timepoint
Day of hospitalization and day of discharge
Method of measurement
Electrolyte analyzer

7

Description
Systemic Blood Pressure
Timepoint
Daily
Method of measurement
Mercury sphygmomanometer

8

Description
General well being
Timepoint
Daily
Method of measurement
Questionnaire. Patients score from 1 to 10 depending on their general well being

9

Description
Peripheral blood malone dialdehyde
Timepoint
Day of hospitalization and day of discharge
Method of measurement
Measurement with hydrochloric acid reagent

10

Description
C Reactive Protein
Timepoint
Day of hospitalization and day of discharge
Method of measurement
Measurement by ELISA sandwich method

Intervention groups

1

Description
Intervention group: Intervention group 1 includes 35 patients with exacerbation of chronic obstructive pulmonary disease who receive 8 mg of dexamethasone injection,eight gram ampules of Iran Hormone Pharmaceutical Company, daily in addition to standard treatment.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group 2 includes 35 patients with exacerbation of chronic obstructive pulmonary disease who, in addition to standard daily treatment, receive 200 mg of injectable hydrocortisone, 100 mg / 2 ml hydrocortisone ampoule made by Alborz Drug Company of Iran , divided into four doses.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajjad Hsp
Full name of responsible person
Moslem Sedaqattalab
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Hormozpoor St. University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Moslem Sedqattalab
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Seyed Ahad Hoseini
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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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Individual data of participants will not be published. Published data can be shared after unidentifiable study subjects.
When the data will become available and for how long
Start access since December 2021
To whom data/document is available
Health researchers as well as reputable pharmaceutical companies
Under which criteria data/document could be used
Health researchers and pharmacy researchers will be able to request information for this study by providing identification documents.
From where data/document is obtainable
Gmail: a.hoseyni80@gmail.com Phone: +989177046952
What processes are involved for a request to access data/document
-Submitting a formal request via e-mail Provide provable proof of authentication Provide the possibility of contacting the relevant university or industrial center Verification by us This process takes a maximum of two weeks.
Comments