

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 receive 8mg IV dexamethasone daily, In addition to standard treatment group2: the patients receive 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

Seyed Ahad Hoseyni

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 2233 0169

##### Email address

a.hoseyni80@gmail.com

##### 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-Boyerahmad

**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**

Cough

### **Timepoint**

Daily

### **Method of measurement**

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

## 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

##### Street address

Hormozpoor St. University of Medical Sciences

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyrhmad

##### Postal code

7591741417

##### Phone

+98 74 3333 7231

##### Email

a.hoseyni80@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Mohamad Amin Qatei

##### Street address

Hormozpoor St. University of Medical Sciences

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyrhmad

##### Postal code

7591741417

##### Phone

+98 74 3333 7231

##### Email

a.hoseyni80@gmail.com

#### 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

Internal Medicine

##### Street address

Hormozpoor St. University of Medical Sciences

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyrhmad

##### Postal code

7591741417

##### Phone

+98 74 3333 7231

##### Email

a.hoseyni80@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Moslem Sedaghattalab

##### Position

Assistant Proffesor

a.hoseyni80@gmail.com

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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7591741417

**Phone**

+98 74 3333 7231

**Email**

a.Hoseyni80@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Seyed Ahad Hoseini

**Position**

Internal Medicine Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

Hormozpoor St. University of Medical Sciences

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591741417

**Phone**

+98 74 3333 7231

**Email**

**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**