

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison and evaluation of the effect of budesonide nebulizer with oral systemic steroids on the amount of peak expiratory flow rate (PEFR) change using peak flowmetry of patients with exacerbated chronic obstructive pulmonary disease (COPD) referred to the emergency department; Non-inferiority Double-Blind Randomized Clinical Trial

Protocol summary

Study aim

Comparison and evaluation of the effect of budesonide nebulizer with oral systemic steroids on the amount of peak expiratory flow rate (PEFR) change using peak flowmetry of patients with exacerbated chronic obstructive pulmonary disease (COPD) referred to the emergency department

Design

Non-inferiority Double-Blind Randomized Phase II Clinical Trial

Settings and conduct

This study is performed on patients with exacerbated COPD that is referred to the emergency service of Imam Khomeini, Shariati and Sina Hospitals. Patients entered into the study will randomly be allocated to intervention and control groups. The intervention group treated with placebo tablets and budesonide nebulizer half a milligrams every 30 minutes to 3 doses and standard treatment. The control group is treated with Prednisolone Fort 50 mg, placebo nebulizer, and standard treatment. Then, patients are assessed for the change in PEFR and FEV1 at 30, 60 minutes, and 3, 6, 12 and 24 hours intervals.

Participants/Inclusion and exclusion criteria

80 patients with moderate to severe COPD following and exacerbated COPD due to respiratory tract infection and aged 15 to 70 years are included and patients with COPD-induced non-respiratory tract infection, history of asthma, allergic rhinitis or atopy, history of systemic corticosteroid of more than 1500 micrograms per day during the previous month, decrease in consciousness, known psychological disorder and inability to cooperate in the study are excluded from the study.

Intervention groups

The intervention group receives a budesonide nebulizer and the control group receives oral systemic steroid.

Main outcome variables

Change in peak expiratory flow rate, Change in FEV1 percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180523039800N1**

Registration date: **2018-10-30, 1397/08/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-30, 1397/08/08**

Update count: **0**

Registration date

2018-10-30, 1397/08/08

Registrant information

Name

Tina Mirrajei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 6136

Email address

tina_mirrajei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15
Expected recruitment end date
 2019-09-06, 1398/06/15
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison and evaluation of the effect of budesonide nebulizer with oral systemic steroids on the amount of peak expiratory flow rate (PEFR) change using peak flowmetry of patients with exacerbated chronic obstructive pulmonary disease (COPD) referred to the emergency department; Non-inferiority Double-Blind Randomized Clinical Trial

Public title
 Evaluation of the effect of budesonide nebulizer in patients with exacerbated COPD

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with exacerbated COPD following respiratory infection 15-70 years old Disease severity of moderate to severe based on GOLD scoring
Exclusion criteria:
 Exacerbated COPD with a cause other than respiratory infection History of asthma, allergic rhinitis or atopy History of systemic corticosteroids more than 1500 micrograms/ day over the past month Patients with decreased consciousness Known psychological disorder and inability to cooperate in the study

Age
 From **15 years** old to **70 years** old

Gender
 Both

Phase
 2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
 Target sample size: **80**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization method: Simple Randomization unit: Individual Stratified randomization is not included
 Randomization Tool: Random number table Allocation concealment: The product and placebo are delivered to the physician with code numbers. Then the treatments will be prescribed to the patient based on a random number table.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In this study, patients, researchers, health care persons including its physician and nurse, and the outcome evaluator are blinded until the end of the study. For this purpose, the patients are divided into an intervention and control group based on the randomization table and the treatment sample or placebo is sent to the physician with a code and the physician performs the treatments according to the product label.

Placebo
 Used
Assignment
 Parallel
Other design features

Secondary Ids
 empty

Ethics committees

1
Ethics committee
Name of ethics committee
 Ethics committee of Tehran University of Medical Sciences
Street address
 Sixth floor, University central building, Qods St, Keshavarz St.
City
 Tehran
Province
 Tehran
Postal code
 1417653761
Approval date
 2018-05-05, 1397/02/15
Ethics committee reference number
 IR.TUMS.MEDICINE.REC.1397.108

Health conditions studied

1
Description of health condition studied
 Chronic obstructive pulmonary disease
ICD-10 code
 J44.1
ICD-10 code description
 Chronic obstructive pulmonary disease with (acute) exacerbation

Primary outcomes

1
Description
 Variation in peak expiratory flow rate
Timepoint
 30 and 60 minutes, and 3, 6, 12, and 24 hours later
Method of measurement

Peak flow meter device

Secondary outcomes

1

Description

Variation in FEV1 percentage

Timepoint

30 and 60 minutes and 3, 6, 12 and 24 hours later

Method of measurement

Spirometry

Intervention groups

1

Description

Intervention group: Budesonide nebulizer (inhaled steroid), Jaber ebne Hayyan Co., 0.5 mg, 3 times, every 30 minutes, and single dose oral placebo tablet

Category

Treatment - Drugs

2

Description

Control group: Oral prednisolone fort (oral systemic steroid), Abu Raihan Co., 50 mg, single dose, and placebo nebulizer, 3 times, every 30 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency services of Tehran University of Medical Sciences

Full name of responsible person

Tina Mirrajei

Street address

Imam Khomeini Hospital, Keshavarz St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Elnaz Vahidi

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evahidi62@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Tina Mirrajei

Position

Medicine residency

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Elnaz Vahidi

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assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be shared after the unidentifiable of the patients

When the data will become available and for how long

6 months after paper publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

In term of analysis the data related to study outcomes

From where data/document is obtainable

tina_mirrajei@yahoo.com

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

The request will be assessed by research committee of Tehran University of Medical Sciences which will be taken around 3 months

Comments