Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 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 budenoside 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)

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+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
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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
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
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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