

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The Effect of Salmeterol, Tiotropium, and their Combination in Patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease (COPD)

Protocol summary

Study aim

The purpose of this study was to determine the effect of salmeterol, tiotropium bromide and its combination in patients with acute exacerbation of COPD.

Design

The randomized clinical trials with single blinded and parallel design in three group.

Settings and conduct

This double-blind study will be conducted on patients with acute exacerbated COPD referred to the Emergency Department of Shahid Beheshti Hospital. Participants in the study will be placed randomly divided into three groups: salmeterol spray, tiotropium bromide capsule, Combination of salmeterol spray and tiotropium bromide capsule.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 35 years and Patients reporting at least 10 packets of cigarette smoking.
Exclusion criteria: Severe associated comorbidities (cardiac and renal) and Patients with prostate hypertrophy and closed glaucoma.

Intervention groups

For intervention group 1 salmeterol spray, intervention 2 an inhalable capsule of tiotropium bromide and intervention 3 a combination will be administered separately for 15 days during admission.

Main outcome variables

Arterial blood gas; COPD severity; dyspnea

General information

Reason for update

Acronym

COPD

IRCT registration information

IRCT registration number: **IRCT20190123042466N1**
Registration date: **2019-04-07, 1398/01/18**

Registration timing: **prospective**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Omid Otroshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

otroshi-om@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-04-25, 1398/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Salmeterol, Tiotropium, and their Combination in Patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease (COPD)

Public title

The Effect of Salmeterol, Tiotropium, and their

Combination in Patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease (COPD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute exacerbation of COPD Age over 35 years Spirometry or previous histories consistent with chronic obstructive pulmonary disease Patients reporting at least 10 packets of cigarette smoking

Exclusion criteria:

Acute coronary syndrome Severe associated comorbidities (cardiac and renal) Patients with a recent history of myocardial infarction Patients with prostate hypertrophy and closed glaucoma Patients with allergic rhinitis or atopy

Age

From **35 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into three groups of 36 people using a computer-generated random numbers and through randomized block design

Blinding (investigator's opinion)

Double blinded

Blinding description

The person analyzing the study data would not know who was receiving the which drug until the end of the data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan University of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2018-12-24, 1397/10/03

Ethics committee reference number

IR.Kaums.REC.1397.085

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Dyspnea in daily living

Timepoint

At the beginning of the study and 15 days after the start of treatment

Method of measurement

The modified Medical Research Council scale

2

Description

Severity of chronic obstructive pulmonary disease

Timepoint

At the beginning of the study and 15 days after the start of treatment

Method of measurement

Chronic obstructive pulmonary disease assessment Test

Secondary outcomes

1

Description

Arterial blood gas parameters

Timepoint

At the beginning of the study and 15 days after the start of treatment

Method of measurement

Arterial blood gases

Intervention groups

1

Description

Intervention group: Salmeterol spray will be used three

times a day with a dose of 25 micrograms for 15 days.

Category

Treatment - Drugs

2**Description**

Intervention group: A thiotropium bromide capsule is given by mouth using Handihaler as an inhaler form twice a day with a dose of 18 micrograms for 15 days

Category

Treatment - Drugs

3**Description**

Intervention group: Combination of salmeterol spray with a dose of 25 micrograms twice a day and a thiotropium bromide capsule at a dose of 18 micrograms once a day for 15 days.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashan Shahid Beheshti Hospital

Full name of responsible person

Mohammad Ali Saba

Street address

Ghotbe Ravandi Boulevard, Kashan University of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Fax

+98 31 5554 0022

Email

Saba-ma@kaums.ac.ir

Web page address

<http://kaums.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Hmidreza Banafshe

Street address

Ghotbe Ravandi Boulevard, Kashan University of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Fax

+98 31 5554 0022

Email

Saba-ma@kaums.ac.ir

Web page address

<http://kaums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

MohammadAli Saba

Position

Pulmonologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Ghotbe Ravandi Boulevard, Kashan University of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Fax

+98 31 5554 0022

Email

aba-ma@kaums.ac.ir

Web page address

<http://kaums.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

MohammadAli Saba

Position

Pulmonologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Ghotbe Ravandi Boulevard, Kashan University of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Fax

+98 31 5554 0022

Email

Saba-ma@kaums.ac.ir

Web page address

<http://kaums.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

MohammadAli Saba

Position

Pulmonologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Ghotbe Ravandi Boulevard, Kashan University of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Fax

+98 31 5554 0022

Email

Saba-ma@kaums.ac.ir

Web page address

<http://kaums.ac.ir/>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is done, After the study is completed

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable