

# 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**

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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**

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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

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## Person responsible for updating data

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MohammadAli Saba

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## 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