

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluation of therapeutic effect of Tiotropium Bromide in early stages of chronic obstructive pulmonary disease in patients of subspecialty clinics of Isfahan university of medical science in 2018 - 2019

#### Protocol summary

##### Study aim

Evaluation of therapeutic effect of Tiotropium Bromide in early stages of chronic obstructive pulmonary disease in patients of subspecialty clinics of Isfahan university of medical science in 2018 - 2019

##### Design

Randomized, controlled, parallel, double-blind clinical trial, phase 3. Sample size is 46 in each group. Randomization by software.

##### Settings and conduct

this research will be hold in Isfahan university of medical sciences clinics in double-blinded (physician and patient) way.

##### Participants/Inclusion and exclusion criteria

1. age 40 - 85 years 2. Hx of COPD GOLD stage 1 ,2 3. FEV1/FVC ratio less than 0.7 after bronchodilator usage.

##### Intervention groups

Intervention group will receive 18 microgram tiotropium bromide inhlaer once daily for 6 months. placebo group will recieve placebo with same shape at the same times. Placebo will be made by pharmacology school. Medications will have no label and none of physician or patients know the type of drug. In next visits clinical situation and spirometry values will be evaluated in one, 3 and 6 months after first visit.

##### Main outcome variables

FEV1 - %FEV1 - FVC - FEV1/FVC

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190524043684N1**

Registration date: **2019-10-13, 1398/07/21**

Registration timing: **prospective**

Last update: **2019-10-13, 1398/07/21**

Update count: **0**

##### Registration date

2019-10-13, 1398/07/21

##### Registrant information

###### Name

Hazhir Moradi Khaniabadi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3222 5089

###### Email address

moradi.hazhir@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-10-22, 1398/07/30

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of therapeutic effect of Tiotropium Bromide in early stages of chronic obstructive pulmonary disease in patients of subspecialty clinics of Isfahan university of medical science in 2018 - 2019

##### Public title

Evaluation of therapeutic effect of Tiotropium Bromide in early stages of chronic obstructive pulmonary disease in

patients of subspecialty clinics of Isfahan university of medical science in 2018 - 201

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

age between 40 - 80 years History of COPD stage GOLD 1 , 2 FEV1 to FVC ratio less than 0.7 after bronchodilator use

### Exclusion criteria:

Not signing informed consent

## Age

From **40 years** old to **85 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor

## Sample size

Target sample size: **92**

## Randomization (investigator's opinion)

Randomized

## Randomization description

patients allocated in two groups of intervention and control randomly by randomizer.org randomization software to produce a random sequence. After allocating a number based on random sequence, even numbers will be assigned to group A and odd numbers to group B.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Placebo will be used in this study. The placebo is completely similar in appearance to the main drug. Medication and placebo are indicated by the letters A and B. The patient, clinical caregiver, and outcome assessor will not know how the letters A and B are assigned to the drug and placebo. Drug and placebo are given by the researcher to the patients.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezar Jarib St.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174373461

##### Approval date

2019-06-04, 1398/03/14

##### Ethics committee reference number

IR.MUI.MED.REC.1398.121

## 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

FEV1

#### Timepoint

0 , 1 , 3 , 6 moths after first visit

#### Method of measurement

spirometry

### 2

#### Description

FVC

#### Timepoint

0 , 1 , 3 , 6 moths after first visit

#### Method of measurement

spirometry

### 3

#### Description

FEV1/FVC

#### Timepoint

0 , 1 , 3 , 6 moths after first visit

#### Method of measurement

spirometry

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: receive 18 micro gram tiotropium

bromide inhaler for 6 moths

**Category**

Treatment - Drugs

**2**

**Description**

Control group: receive placebo for 6 months

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Isfahan University of medical sciences clinics

**Full name of responsible person**

Dr. Tahereh Changiz

**Street address**

Hezar jerib

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8174673461

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info@mui.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Tahereh Changiz

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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**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Farzin Ghiasi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Alzahra Hospital , Soffeh st.

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

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**Phone**

+98 31 3620 2020

**Email**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hazhir Moradi Khaniabadi

**Position**

Medical Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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**Fax**

### Email

moradi.hazhir@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**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**

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

**Data Dictionary**

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