

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)

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+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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Hazhir Moradi Khaniabadi

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

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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