

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Efficacy of Tiotropium compared with salmeterol in control of dynamic hyperinflation in patients with chronic obstructive pulmonary disease admitted to Imam Reza Hospital,Tabriz

Protocol summary

Summary

In this study ,From first day of August 2011 to the end of March 2012 all patients referred to pulmonology clinic of Imam Reza Hospital with a diagnosis of COPD in the early stages (stages 1, 2) and after obtaining entry and exit criteria, were randomly divided into two groups with Tiotropium (only Tiotropium with 18 microgram per day via inhalation) and the classical treatment group (salmeterol 50 microgram twice daily via inhalation) are classified in the Shadow of a baseline spirometry to measure IC and RV / TLC with Body Box spirometry , and after two months of the treatment again and repeat the above results will be compared for dynamic hyperinflation. Total number of patients about 80 .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201098659N1**
Registration date: **2012-02-29, 1390/12/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-29, 1390/12/10

Registrant information

Name

Payam Salehirad

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Science

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-09-26, 1391/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Tiotropium compared with salmeterol in control of dynamic hyperinflation in patients with chronic obstructive pulmonary disease admitted to Imam Reza Hospital,Tabriz

Public title

Effect of Tiotropium in Patients with Chronic Obstructive Pulmonary Diseases

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:(Patient with early stages of COPD ;Men and Weman between 40 to 80 years old.) Exclusion criteria:(Patients under 40 and above 80 ;Patients with a history of asthma ;lung Lobectomy history ;cystic fibrosis ;patients treated with inhaled or oral corticosteroids in the previous three months : patients with other diseases associated with clinical problems in their daily activities ; also to make it still more complications possible heart attack in the use of this drug is definitely ruled out,

people with heart problems, will be excluded from the study.) .

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Department of Research and Technology A
productivity, Third Floor, Central Building No. 2 ,
Golgasht st. , Tabriz

City

Tabriz

Postal code

Approval date

2012-01-08, 1390/10/18

Ethics committee reference number

5/4/8134

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Diseases

ICD-10 code

J40,J47

ICD-10 code description

Chronic Lower Respiratory Diseaes

Primary outcomes

1

Description

Dynamic Hyperinflation measurements

Timepoint

Before and Two months after completion of drug

Method of measurement

Study Of Lung Volumes using Spirometry

Secondary outcomes

empty

Intervention groups

1

Description

First Group therapy with Tiotropium (only Tiotropium18
microgram per day via inhalation for two months)

Category

Treatment - Drugs

2

Description

Second Group : Classical therapy (with Salmeterol 50
microgram twice daily via inhalation for two months)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Subspeciality Lung Disease Clinic of Imam Reza
Hospital, Tabriz

Full name of responsible person

Salehirad Payam

Street address

Lung ward , Fourth floor , Imam Reza Hospital ,
Golgasht st., Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ansarin Khalil

Street address

Tuberculosis and Lung Diseases Research Center ,
Imam Reza Hospital , Golgasht st. , Tabriz

City

Tabriz

Grant name

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Salehirad Payam

Position

Pulmonary and Critical Care Fellowship

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty