

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Study of the effectiveness of Tiotropium bromide in patients with severe asthma

Protocol summary

Study aim

Evaluation of the effectiveness of Tiotropium bromide in patients with severe asthma

Design

Randomized Placebo_controlled , Crossover and double blinded Trial

Settings and conduct

After obtaining approval from the Ethics Committee, patients are randomly assigned to two groups of placebo and intervention. In the intervention group, in addition to routine treatment, Tiotropium bromide is prescribed. After 4 weeks, the variables are checked in two groups and after a 4-week washout period, the group that receive the placebo receive the drug (Tiotropium bromide) , and the group receiving the drug Tiotropium bromide receives placebo and after a 4-week period, the variables are re_evaluated in two groups. Thiotropium bromide and placebo are named as code, and health care personnel and patients are not aware of the type.

Participants/Inclusion and exclusion criteria

Entering conditions: Patients with severe asthma who have been treated with routine anti-asthma drugs and Being under treatment with routine anti-asthma drugs and Labeled as grade 4 or 5 of asthma. Not-entering conditions: Pregnancy lactation (Breastfeeding) Using hormonal contraceptives drugs High pregnancy probability Chronic obstructive pulmonary disease (COPD) Having other pulmonary diseases Infection of the respiratory system Audio cord performance dysfunction smokers with more than 10 pack per year History of taking muscarinic anticholinergic drugs History of taking other anticholinergic drugs Inability to use the drugs prescribed in this study

Intervention groups

Patients are divided into two groups of placebo and intervention. In the intervention group, in addition to routine treatment, Tiotropium bromide is prescribed.

Main outcome variables

Forced expiratory volume in 1 second (FEV1) ,asthma

control test (ACT) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181015041353N1**

Registration date: **2018-11-01, 1397/08/10**

Registration timing: **prospective**

Last update: **2018-11-01, 1397/08/10**

Update count: **0**

Registration date

2018-11-01, 1397/08/10

Registrant information

Name

Seyed Mohammad Ali Mir Jahanbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5564

Email address

dr.mirjahan@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effectiveness of Tiotropium bromide in patients with severe asthma

Public title

The effectiveness of Tiotropium bromide in patients with severe asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with severe asthma who have been treated with routine anti-asthma drugs Being under treatment with routine anti-asthma drugs Labeled as grade 4 or 5 of asthma Age of 18 years and more

Exclusion criteria:

Pregnancy lactation (Breastfeeding) Using hormonal contraceptives drugs High pregnancy probability Chronic obstructive pulmonary disease (COPD) Having other pulmonary diseases Infection of the respiratory system Audio cord performance dysfunction smokers with more than 10 pack per year History of taking muscarinic anticholinergic drugs History of taking other anticholinergic drugs Inability to use the drugs prescribed in this study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to either placebo group or intervention using permuted block randomization. Permuted block randomization is a way to randomly allocate a participant to a treatment group, while maintaining a balance across treatment groups. Each "block" has a specified number of randomly ordered treatment assignments.

Blinding (investigator's opinion)

Double blinded

Blinding description

Samples and clinical personnel (physicians , nurses ,physiotherapists and etc) who have responsibility of taking care of the patients and who ever has any direct contact with samples are blinded and researcher and and evaluator and The Data and Safety Monitoring Board (DSMB) are not blinded.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

ZAUMS Main campus, Zahedan, Sistan and Baluchestan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463i

Approval date

2018-08-12, 1397/05/21

Ethics committee reference number

IR.ZAUMS.REC.1397.199

Health conditions studied

1

Description of health condition studied

Moderate persistent asthma with status asthmaticus

ICD-10 code

J45.42

ICD-10 code description

Moderate persistent asthma with status asthmaticus

2

Description of health condition studied

Severe persistent asthma

ICD-10 code

J45.5

ICD-10 code description

Severe persistent asthma

Primary outcomes

1

Description

Forced expiratory volume in 1 second (FEV1)

Timepoint

At the beginning and after Four weeks of phase one, and four weeks after the start of phase two. Between the two phases is a four weeks long washout period.

Method of measurement

Spirometry

2

Description

asthma control test (ACT) score

Timepoint

At the beginning and after Four weeks of phase one, and four weeks after the start of phase two. Between the two phases is a four weeks long washout period.

Method of measurement

By test score

Secondary outcomes

1

Description

The need for oral or injection of steroids

Timepoint

At the beginning and after Four weeks of phase one, and four weeks after the start of phase two. Between the two phases is a four weeks long washout period.

Method of measurement

By the physician

2

Description

Need of hospitalization

Timepoint

At the beginning and after Four weeks of phase one, and four weeks after the start of phase two. Between the two phases is a four weeks long washout period.

Method of measurement

By the physician

Intervention groups

1

Description

Intervention group: Name of drug : Capsule - Inhalation Tiotropium bromide 18 micrograms daily (one puff daily) for 4 weeks separately in phase 1 and 2, Made in India by CIPA

Category

Treatment - Drugs

2

Description

Control group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Lung clinic of Ali Ibne Abitaleb Hospital

Full name of responsible person

Dr.Nazar Ali Moulaei

Street address

Salamat Blvd., Persian Gulf Highway, Zahedan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr.Noor Mohammad Bakhshani

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Web page address

<http://zaums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Seyed Mohammad Ali Mir Jahanbakhsh

Position

Internal Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Internal Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Fax

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