

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Reduction of steroid inhaler dose in comparison with Montelukast discontinuation in asthma patients controlled by steroid inhaler and Montelukast

Protocol summary

Summary

Asthma controlled patients by steroid inhaler and Montelukast will be recruited from Imam Khomeini pulmonary clinic. All patients enrolled in this study after explaining study goals and methods and getting their informed consent. Their demographic data and all past medical history will be recorded in designed forms. Patients will be randomized by four block randomization methods in A and B groups. In A group steroid inhaler dose will be halved and other medications will be continued. In B group Montelukast will be discontinued and steroid inhaler and other medications will be continued. All patients will be visited in the pulmonary clinic at months 1 and 3 and ACT questionnaire and spirometry will be done in each visit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052428037N1**

Registration date: **2016-07-01, 1395/04/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-01, 1395/04/11

Registrant information

Name

Hamidreza Abtahi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2646

Email address

hrabtahi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Dr.Abidi Pharmaceutical Company

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Reduction of steroid inhaler dose in comparison with Montelukast discontinuation in asthma patients controlled by steroid inhaler and Montelukast

Public title

Comparison of two methods of asthma medication reduction in patients with controlled asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1: Asthmatic patients with Asthma Control Test (ACT) >20 and FEV1> 80% predicted in two sequential visits 2: Age >18 years old 3.Asthma symptoms>1 year 4: Use of asthma controller medications >3 months 5: At least 2 monthly visits by his/her physician in Imam Khomeini pulmonary clinic
Exclusion Criteria: 1: Use of systemic steroids or emergency visit in the past 3 months due to asthma exacerbation 2: Pregnancy 3: Inability or unwillingness

for scheduled visits by his/her physician 4: Patients request for increase in the asthma medication after enrolling in this study

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Tehran Univcityof Medical Science

Street address

Tehran Univcityof Medical Science

City

Tehran

Postal code

Approval date

2016-05-15, 1395/02/26

Ethics committee reference number

94-03-159-30560

Health conditions studied

1

Description of health condition studied

asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Asthma control Rate

Timepoint

3 months

Method of measurement

Asthma Control Tool and Spirometry

Secondary outcomes

1

Description

Exacerbation numbers

Timepoint

during study

Method of measurement

Emergency visit due to exacerbation

Intervention groups

1

Description

In A group steroid inhaler dose will be halved and other medication will be continued

Category

Treatment - Drugs

2

Description

In B group Montelukast will be discontinued and steroid inhaler and other medication will be continued

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini pulmonary clinic

Full name of responsible person

Dr. Rahimi

Street address

Imam Khomeini pulmonary clinic

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dr.Abidi Pharmaceutical Company

Full name of responsible person

Amir Razavian

Street address

Dr.Abidi Pharmaceutical Company
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dr.Abidi Pharmaceutical Company
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
Tehran University of Medical Science
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Position
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Other areas of specialty/work
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Person responsible for updating data

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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