

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Subjective response to inhaled steroid in patients with clinically suspected asthma and negative methacholine challenge test

Protocol summary

Summary

1.Objectives: Evaluation of subjective response, using a course of empiric treatment in clinically suspected asthma despite negative paraclinic tests . 2.Design: Patients with high clinical probability of asthma despite negative methacholine test will receive a trial of treatment for assessing before and after subjective response. This also may be a diagnostic mean for confirming asthma. 3.Setting and conduct: after 2 weeks run in period, patients will be treated with 12 weeks course of inhaled Fluticasone. 4.Participants including major eligibility criteria: Patients with mild to moderate persistent complaints, that are highly suggestive of asthma,will be included in this study. Those with history and physical examination or imaging compatible with other diagnosis or environmental toxic exposure will be excluded from study. 5.Intervention: Flixotide (gsk, Australia) in metered dose inhaler (MDI) with dose of 250 µg 2 puff BID for 12 weeks 6.Main outcome measures variables: evaluating before and after treatment subjective response with "Asthma Control Test" and "numeric cough score".

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202297795N1**
Registration date: **2012-03-23, 1391/01/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-23, 1391/01/04

Registrant information

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Soheil Peiman

Name of organization / entity

Tehran University of Medical Science, Imam Hospital

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-02-15, 1390/11/26

Expected recruitment end date

2012-05-01, 1391/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Subjective response to inhaled steroid in patients with clinically suspected asthma and negative methacholine challenge test

Public title

Asthma treatment in patients with negative Methacholine test

Purpose

Diagnostic

Inclusion/Exclusion criteria

Study inclusion criteria : 1. high clinical probability of asthma; 2.Normal chest-x-ray; 3.Normal spirometry; 4.Negative methacholine challenge test; 5.Symptoms for at least 2 month; 6.Those who complete treatment course and follow up; Study Exclusion criteria: 1.Low

clinical probability of asthma; 2.Abnormality in imaging and spirometry; 3.More than 20 pack year smoking; 4.Prominent medical disease; 5.Significant occupational injury; 6.Those who do not complete treatment course and follow up;

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of medical sciences

Street address

6th floor, central organization of Tehran university of medical sciences, ghods street,

City

Tehran

Postal code

Approval date

2012-02-15, 1390/11/26

Ethics committee reference number

130/2251

Health conditions studied

1

Description of health condition studied

Asthma/Airway hyperactivity symptoms

ICD-10 code

J45.8

ICD-10 code description

Combination of Nonallergic asthma and allergic asthma

Primary outcomes

1

Description

Asthma Control Test questionnaire Score

Timepoint

12 weeks

Method of measurement

questionnaire

2

Description

Numeric Cough Score

Timepoint

12 weeks

Method of measurement

questionnaire

Secondary outcomes

1

Description

General satisfaction of patients

Timepoint

after 12 weeks

Method of measurement

ACT questionnaire (question number 5) score

Intervention groups

1

Description

12 weeks course of inhaled Fluticasone (Flixotide®- GlaxoSmithKline Australia) in metered dose inhaler (MDI) with dose of 250 µg 2 puff BID

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor Respiratory clinic

Full name of responsible person

Street address

Noor Day clinic, Motahhari street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Tehran University of Medical Sciences

Street address

Floor 4, Central organization of Tehran university of medical sciences, Ghods street, Keshavaez blv, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Tehran university of medical science, Imamkhomeini medical center

Full name of responsible person

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Position

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Other areas of specialty/work

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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