

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Prevalence of aspirin sensitivity in patients with moderate to severe asthma according to the response to 3 months asthma standard therapy

Protocol summary

Summary

Objective: Prevalence of aspirin sensitivity in patients with moderate to severe asthma according to the response to 3 months asthma standard therapy. Design: Single arm study, not blinded, placebo not used, single center. Major Inclusion criteria: Patients 18 to 65 years old with moderate to severe asthma based on history, spirometric findings and Expert Panel Report 3 (EPR-3) guidelines. Major Exclusion criteria: Patients with serious underlying disease; medical history of immediate hypersensitivity reactions to aspirin and nonsteroidal anti-inflammatory drugs; Forced Expiratory Volume in the first second (FEV1) less than 70% at the time of aspirin challenge; pregnancy; breast-feeding; using of medication interfering with the aspirin challenge. Sample size: 100 patients. Intervention: Patients are treated with asthma standard treatment for 3 months according to the EPR-3 guidelines including inhaled corticosteroids and inhaled long-acting bronchodilators (fluticasone-salmeterol 250/50 microgram) and if necessary montelukast or oral corticosteroids (prednisolone) and treatment of comorbidities such as gastroesophageal reflux disease and rhinosinusitis if required. Main outcome measures: Evaluation of asthma symptoms according to standard questionnaire ACT (Asthma Control Test), pulmonary function based on spirometry test and monitored for treatment side effect according to questionnaire are performed at first and after 3 months of study. At the end of 3 months, after obtaining informed consent, aspirin challenges are performed for them and the prevalence of aspirin sensitivity in moderate to severe asthma are evaluated according to the asthma control (based on ACT score and spirometric findings) after 3 months of asthma standard therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042721970N1**

Registration date: **2015-07-29, 1394/05/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-29, 1394/05/07

Registrant information

Name

Saba Arshi

Name of organization / entity

Iran University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prevalence of aspirin sensitivity in patients with moderate to severe asthma according to the response to

3 months asthma standard therapy	Tehran
Public title	Postal code
Prevalence of aspirin sensitivity in moderate to severe asthma according to the response to 3 months asthma standard therapy	Approval date
Purpose	2015-04-18, 1394/01/29
Diagnostic	Ethics committee reference number
Inclusion/Exclusion criteria	105/227/94/3
Inclusion criteria: 18 to 65 years old; moderate to severe asthma according to the history and spirometric findings and EPR-3 (Expert Panel Report 3) guidelines Exclusion criteria: Presence of serious underlying disease such as bleeding disorders, gastrointestinal, rheumatologic, cancer, heart, kidney, liver and mental diseases; medical history of immediate hypersensitivity reactions to aspirin and nonsteroidal anti-inflammatory drugs; Forced Expiratory Volume in the first second (FEV1) less than 70% at the time of aspirin challenge; pregnancy; breast-feeding; the use of systemic and topical beta-blocker, angiotensin-converting enzyme inhibitor, angiotensinogen II receptor blocker, warfarin; mastocytosis; nonadherent patients; patients with high risk jobs or lifestyle	Health conditions studied
Age	<u>1</u>
From 18 years old to 65 years old	Description of health condition studied
Gender	Asthma
Both	ICD-10 code
Phase	J45.8
N/A	ICD-10 code description
Groups that have been masked	Mixed asthma Combination of conditions listed in J45.0 and J45.1
No information	Primary outcomes
Sample size	<u>1</u>
Target sample size: 100	Description
Randomization (investigator's opinion)	Asthma symptoms
N/A	Timepoint
Randomization description	At first and after 3 months of study
Blinding (investigator's opinion)	Method of measurement
Not blinded	Standard questionnaire "Asthma Control Test"
Blinding description	<u>2</u>
Placebo	Description
Not used	Pulmonary function
Assignment	Timepoint
Single	At first and after 3 months of study
Other design features	Method of measurement
	Spirometry test
Secondary Ids	Secondary outcomes
empty	<u>1</u>
Ethics committees	Description
<u>1</u>	Asthma standard treatment side effect: mouth thrush
Ethics committee	Timepoint
Name of ethics committee	Monthly
Ethics committee of Iran University of Medical Sciences	Method of measurement
Street address	Questionair
Iran University of Medical Science, Hemmat highway, Tehran	<u>2</u>
City	Description
	Asthma standard treatment side effect: hoarseness
	Timepoint
	Monthly
	Method of measurement
	Questionnaire
	Intervention groups

1

Description

Standard treatment of moderate to severe asthma based on EPR-3 guidelines, include inhaled corticosteroids, inhaled long acting bronchodilators (for moderate asthma: Fluticasone-Salmeterol 250/50 microgram oral inhaler (Salmeflo "SADAF DAROU SABA") 1 puff every 12 hours and for severe asthma: Fluticasone-Salmeterol 250/50 microgram oral inhaler (Salmeflo "SADAF DAROU SABA") 2 puff every 12 hours) and if necessary montelukast 10 mg (Abidi) daily or oral corticosteroids (prednisolone) and treatment of comorbidities such as gastroesophageal reflux disease and rhinosinusitis if required.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy and clinical immunology department of Rasool Akram hospital

Full name of responsible person

Dr Narges Eslami, fellowship of allergy and clinical immunology

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City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr Seyyed Ali Javad Mosavi, Deputy of Research and Technology

Street address

Iran University of Medical Science, Hemmat highway, 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, Iran 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

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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