Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran Uiversity 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

Public title
Prevalence of aspirin sensitivity in moderate to severe asthma according to the response to 3 months asthma standard therapy
Purpose
Diagnostic
Inclusion/Exclusion criteria
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 ‖ receptor blocker, warfarin; mastocytosis; nonadherent patients; patients with high risk jobs or lifestyle
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
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 Iran University of Medical Sciences
Street address
Iran University of Medical Science, Hemmat highway, Tehran
City
Tehran
Postal code
Approval date
2015-04-18, 1394/01/29
Ethics committee reference number
105/227/94/ذ

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45.8
ICD-10 code description
Mixed asthma Combination of conditions listed in J45.0 and J45.1

Primary outcomes

1

Description
Asthma symptoms
Timepoint
At first and after 3 months of study
Method of measurement
Standard questionnaire "Asthma Control Test"

2

Description
Pulmonary function
Timepoint
At first and after 3 months of study
Method of measurement
Spirometry test

Secondary outcomes

1

Description
Asthma standard treatment side effect: mouth thrush
Timepoint
Monthly
Method of measurement
Questionair

2

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

Street address
Allergy and clinical immunology department, Rasool Akram hospital, Niyayesh avenue, Sattarkhan street, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Iran Uiversity 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 Uiversity 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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Full name of responsible person
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Position
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Person responsible for updating data

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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