Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Clinical trial comparing the effects of low dose aspirin and placebo on clinical improvement of moderate to severe aspirin-sensitive asthmatic patients with chronic rhinosinusitis and nasal polyposis

Protocol summary

Summary

Objective: Comparing effects of low dose aspirin and placebo on clinical improvement of moderate to severe aspirin sensitive asthmatic patients with chronic rhinosinusitisl (CRS) and nasal polyposis Design: Balanced Block Randomization, double blinded, placebo used, single center, trial phase 2 Major Inclusion criteria: 18 to 65 years old patients with moderate to severe aspirin sensitive asthma with CRS and nasal polyposis based on history, physical exam, spirometric and sinus CT scan findings and Expert Panel Report 3 (EPR-3) guidelines and receiving rhinosinusitis and asthma standard treatments (according to the EPR-3 guidelines) for 3 months. Major Exclusion criteria: 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; using of medication interfering with aspirin challenge Sample size: 10 patients in each treatment group (totally: 30 patients) Interventions: Aspirin challenge is performed after obtaining informed consent .Those with positive aspirin challenge are desensitized and randomly and blindly are placed in 3 treatment groups with 100 mg aspirin daily, 325 mg aspirin daily or placebo daily for 6 months. Patients and physicians are not aware of 3 treatment groups. Main outcome measures: Evaluation of asthma symptoms according to the ACT questionnaire, spirometric findings and treatment side effects before and after 3 and 6 months of intervention and the effects of low dose aspirin and placebo on clinical improvement of moderate to severe aspirin-sensitive asthmatic patients with CRSand nasal polyposis are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061521970N2**
Registration date: **2015-07-27, 1394/05/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-27, 1394/05/05

Registrant information

Name

Saba Arshi

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 6435 2383

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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
Clinical trial comparing the effects of low dose aspirin and placebo on clinical improvement of moderate to severe aspirin-sensitive asthmatic patients with chronic rhinosinusitis and nasal polyposis

Public title
The effect of aspirin in treatment of moderate to severe aspirin-sensitive asthmatic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 18 to 65 years old; clinical symptoms of chronic rhinosinusitis with nasal polyposis which confirmed by sinus CT scan; moderate to severe asthma according to the history, spirometric findings and Expert Panel Report 3 (EPR-3) guidelines; receiving the full course of standard treatments for rhinosinusitis and asthma according to the EPR-3 guidelines for 3 months before entering study 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
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Balanced Block Randomization

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/د IR.IUMS.REC.1394

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

2

Description of health condition studied
Chronic rhinosinusitis

ICD-10 code
J32

ICD-10 code description
J32 (abscess empyema infection suppuration) (chronic) of sinus (accessory)(nasal)

3

Description of health condition studied
Nasal polyposis

ICD-10 code
J33

ICD-10 code description
Nasal polyposis

Primary outcomes

1

Description
Asthma symptoms

Timepoint
After 3 and 6 months

Method of measurement
Standard questionnaire "Asthma Control Test"

2

Description
Pulmonary function

Timepoint
After 3 and 6 months
Method of measurement
Spirometry test

Secondary outcomes

1

Description
Aspirin side effect: bleeding
Timepoint
Monthly
Method of measurement
Questionnaire

2

Description
Aspirin side effect: gastrointestinal disturbance
Timepoint
Monthly
Method of measurement
Questionnaire

3

Description
Asthma standard treatment side effect: hoarseness
Timepoint
Monthly
Method of measurement
Questionnaire

4

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

Intervention groups

1

Description
Intervention group: tab aspirin 100 mg, daily for 6 months
Category
Treatment - Drugs

2

Description
Intervention group:tab aspirin 325 mg, daily for 6 months
Category
Treatment - Drugs

3

Description
Control group: placebo, daily for 6 months
Category
Placebo

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
Allergy and clinical immunology department of Rasool Akram hospital

Full name of responsible person
Dr Narges Eslami

Position
Fellowship of Allergy and clinical immunology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person
Dr Saba Arshi

Position
Head of Allergy and clinical immunology department

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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