

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 rhinosinusitis (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 CRS and 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)

Phone

+98 21 6435 2383

Email address

arshi.s@iums.ac.ir

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

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 II 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/ 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 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

Allergy and clinical immunology department of Rasool Akram hospital

Full name of responsible person

Dr Narges Eslami

Position

Fellowship of Allergy and clinical immunology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr Saba Arshi

Position

Head of Allergy and clinical immunology department

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Allergy and clinical immunology department of Rasool Akram hospital

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Fellowship of allergy and clinical Immunology

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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