

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Study of the prevalence of aspirin sensitivity in patients with chronic rhinosinusitis and nasal polyposis coming to allergy department of Rasool-e-Akram hospital according to response to standard treatment after three months.

Protocol summary

Summary

objectives: study of the prevalence of aspirin sensitivity in patients with chronic rhinosinusitis and nasal polyposis according to response to standard treatment after three months. Study design: a phase 2, single center, non randomized, non placebo controlled, non blinded, clinical trial. Methods: patients aging 18-65 years old with chronic rhinosinusitis and nasal polyposis undergo treatment with intranasal beclometasone twice a day, 10 miligram montelukast, 10 miligram cetirizine, 50 miligram prednisolone daily and nasal rinse, after paranasal sinuses computed tomography scan and SNOT questionnaire are completed. then aspirin challenge will be done. Inclusion criteria: age 18-65 years old; symptoms of chronic rhinosinusitis with nasal polyps which is documented on CT scan. Exclusion criteria: serious underlying disease such as bleeding tendency, gastrointestinal, rheumatologic, malignancy, cardiac, renal, hepatic, psychological; history of IgE mediated reactions to aspirin or nonsteroidal anti inflammatory drugs; first second expiratory volume of more than 70 percent of predicted before aspirin challenge test; pregnancy; breast feeding; use of topical and systemic beta blockers; use of warfarin; mastocytosis; patients with poor adherence. Sample size: 100 patients. Interventions: single intervention group including intranasal beclometasone, daily montelukast, cetirizine, prednisolone and aspirin challenge after three months. Primary outcome: rhinosinusitis symptom severity. Secondary outcome: complications of treatment such as epistaxis, nasal burning, septal perforation, drowsiness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061322531N1**

Registration date: **2015-07-22, 1394/04/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-07-22, 1394/04/31

Registrant information

Name

Mohamad Nabavi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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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

2015-12-23, 1394/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the prevalence of aspirin sensitivity in patients with chronic rhinosinusitis and nasal polyposis coming to allergy department of Rasool-e-Akram hospital according to response to standard treatment after three months.

Public title

Study of the prevalence of aspirin sensitivity in patients with chronic rhinosinusitis and nasal polyposis coming to allergy department of Rasool-e-Akram hospital according to response to standard treatment after three months.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: age 18-65 years old; presence of symptoms of chronic rhinosinusitis with nasal polyps which is documented on CT scan. Exclusion criteria: existence of any serious underlying disease such as bleeding tendency, gastrointestinal, rheumatologic, malignancy, cardiac, renal, hepatic, psychological; history of IgE mediated reactions to aspirin or nonsteroidal anti inflammatory drugs; first second expiratory volume of more than 70 percent of predicted before aspirin challenge test; pregnancy; breast feeding; use of topical and systemic beta blockers; use of warfarin and warfarin derivatives; mastocytosis; patients with poor cooperation and poor adherence.

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: **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

Iran University of Medical Sciences

Street address

Fifth floor, Central Cental Building, Iran University of

Medical Sciences, between Chamran and Sheikh Fazlollah highway, Hemmat Highway, Tehran.

City

Tehran

Postal code

Approval date

2015-04-18, 1394/01/29

Ethics committee reference number

105/228/94/3

Health conditions studied

1

Description of health condition studied

chronic rhinosinusitis with nasal polyposis

ICD-10 code

J33.8

ICD-10 code description

Other polyp of sinus Polyp of sinus: accessory ethmoidal maxillary sphenoidal

Primary outcomes

1

Description

severity of symptoms of chronic rhinosinusitis with nasal polyposis

Timepoint

after 3 months

Method of measurement

Sino Nasal Outcome Test (SNOT) questionnaire

Secondary outcomes

1

Description

complications of conventional treatment including epistaxis, nasal burning sensation, nasal septal perforation, feeling sleepy

Timepoint

before intervention, three months after intervention.

Method of measurement

history taking

Intervention groups

1

Description

one intervention group which includes conventional treatment for chronic rhinosinusitis with nasal polyposis including intranasal beclomethasone one puff in each nostril twice per day, nasal saline rinse with 5 milliliter of saline three times a day, 10 milligram montelukast tablet once daily, 10 milligram cetirizine tablet once daily for three consecutive months and a 10 days course of prednisolone 50 milligrams per day, and aspirin challenge test after three months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Allergy department of rasool-e-akram hospital

Full name of responsible person

Sima Shokri

Street address

Fourth floor, Building number one, Rasool-e-Akram hospital, Niayesh street, Satrkhan Avenue,

City

Tehran

Position

Allergy and clinical immunology fellow

Other areas of specialty/work**Street address**

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vce chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Mousavi

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Department of internal medicine, seventh floor, Rasool-e-akram ospital-Niayesh street-Sattarkhan avenue.

City

Tehran

Grant name

-

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vce chancellor for research of 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**

Iran University of Medical Sciences

Full name of responsible person

Sima Shokri

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Associated professor

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Web page address**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