

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Study of the therapeutic effect of low dose aspirin on symptoms of chronic rhinosinusitis and nasal polyposis with aspirin sensitivity

Protocol summary

Summary

Objectives: Study of the therapeutic effect of low dose aspirin on symptoms of chronic rhinosinusitis and nasal polyposis with aspirin sensitivity. Study design: a randomized double blind placebo controlled single center phase 2 clinical trial. Settings and conduct: Inclusion criteria: age of 18-65 years; three months of conventional treatment before aspirin challenge; symptoms of chronic rhinosinusitis with nasal polyposis confirmed by CT scan; Exclusion criteria: hemorrhagic; gastrointestinal; rheumatologic; malignant; cardiovascular; renal; hepatic and psychological disorders; history of IgE mediated reactions to aspirin or other non steroidal anti inflammatory drugs; first second expiratory volume of less than 70 percent of predicted at the time of aspirin challenge; pregnancy; nursing; use of beta blockers, warfarin, Angiotensin converting enzyme inhibitors; poor cooperation, patients with high risk of trauma and accidents. Sample size: sixty patients. Intervention: three intervention groups including aspirin desensitization and then: Group1: aspirin tablet 325 milligrams daily added to conventional treatment including intranasal beclomethasone one puff per nostril twice a day, nasal rinse with five milliliter of saline three times a day, 10 milligram montelukast tablet once daily, 10 milligram cetirizine tablet once daily, all for six months period. Group2: aspirin tablet 100 milligrams daily added to conventional treatment. Group3: placebo tablet once daily, for which the composition is the same as Aspirin tablet except for active aspirin material, added to conventional treatment. Main outcome measure: symptoms of rhinosinusitis according to SNOT questionnaire and CT scan.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015061522531N2**

Registration date: **2015-08-20, 1394/05/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-20, 1394/05/29

Registrant information

Name

Mohamad Nabavi

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the therapeutic effect of low dose aspirin on symptoms of chronic rhinosinusitis and nasal polyposis with aspirin sensitivity

Public title

Study of the therapeutic effect of low dose aspirin on symptoms of chronic rhinosinusitis and nasal polyposis with aspirin sensitivity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 18-65 years; achieving a course of three months of conventional treatment before aspirin challenge; presence of symptoms of chronic rhinosinusitis with nasal polyposis confirmed by CT scan; Exclusion criteria: presence of any serious underlying disease including hemorrhagic; gastrointestinal; rheumatologic; malignant; cardiovascular; renal; hepatic and psychological disorders; history of IgE mediated reactions to aspirin or other non steroidal anti inflammatory drugs; first second expiratory volume of less than 70 percent of predicted at the time of aspirin challenge; pregnancy; nursing; use of topical or systemic beta blockers; warfarin and its derivatives; Angiotensin converting enzyme inhibitors; patients with poor cooperation or treatment adherence; patients with carriers with high risk of trauma and accidents;

Age

From **17 years** old to **64 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Iran University of Medical Sciences

Street address

Fifth floor, Central Setad building, between Chamran and Sheikh Fazlollah Highway, Hemmat Highway, Iran University of Medical Sciences

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 sphenoida

Primary outcomes

1

Description

severity of symptoms of chronic rhinosinusitis with nasal polyposis

Timepoint

before intervention, three months and six months after intervention

Method of measurement

SinoNasal Outcome Test questionnaire and paranasal sinus CT scan

Secondary outcomes

1

Description

complications of aspirin including gastrointestinal discomfort, epigastric pain or burning, nausea, vomiting, gastro intestinal bleeding, easy bruising, bleeding with minor trauma

Timepoint

before intervention, three and six months after intervention

Method of measurement

history taking and physical examination

Intervention groups

1

Description

Intervention group1: aspirin desensitization and then prescription of aspirin with a daily dose of 325 milligrams added to conventional treatment including intranasal beclomethasone one puff per nostril twice a day, nasal rinse with five milliliter of saline three times a day, 10 milligram montelukast tablet once daily, 10 milligram cetirizine tablet once daily, all for six months period

Category

Treatment - Drugs

2**Description**

Intervention group 2: Aspirin desensitization and then perscription of aspirin with a daily dose of 100 milligram added to conventional treatment including intranasal beclomethasone one puff per nostril twice a day, nasal rinse with five milliliter of salin three times a day, 10 milligram montelukast tablet once daily, 10 milligram cetirizine tablet once daily, all for six months period

Category

Treatment - Drugs

3**Description**

Control: Aspirin desensitization and then perscription of placebo tablet once daily, for which the composition is the same as Aspirin tablet except for active aspirin material, added to conventional treatment including intranasal beclomethasone one puff per nostril twice a day, nasal rinse with five milliliter of salin three times a day, 10 milligram montelukast tablet once daily, 10 milligram cetirizine tablet once daily, all for six months period

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, Sattarkhan Avenue.

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, 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 Hospital, 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

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**

Iran University of Medical Sciences

Full name of responsible person

Sima Shokri

Position

Allergy and clinical immunology fellow

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

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Person responsible for scientific 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