Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the theraputic 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

Iran (Islamic Republic of)

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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 theraputic effect of low dose aspirin on symptoms of chronic rhinosinusitis and nasal polyposis with aspirin sensitivity

Public title
Study of the theraputic 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 derivates; 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.د

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 minths after intervention
Method of measurement
SinoNasal Outcome Test questionnaire and paranasa sinus CT scan

Secondary outcomes

1

Description
complications of aspirin including gastrointestinal dyscomfort, epigastric pain or burning, nausea, vomitting, 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 perscription of aspirin with a daily dose of 325milligrams 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

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 placcebo 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
Tehran

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
Street address
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
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Person responsible for scientific inquiries

Contact
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Mohamad Nabavi
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associated professor
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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