Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

comparison of frequency of aspirin hypersensitivity in people with and without nasal polyps

Protocol summary

Summary

We want to compare the frequency of aspirin hypersensitivity in people with and without nasal polyps. in this study, we select 2 group of people in range of 18-60 years old. The first group is patients who referred to ENT service in Rasht, Amiralmomenin hospital and diagnosis of nasal polyps is definite for them by endoscopy or CTs, and the second group select from healthy people (without the nasal polyps). The size of the samples is 48 in each group.In both group oral aspirin challenge test is done.Those with contraindications for oral aspirin challenge test (a history of very severe anaphylactic reaction,severe disease of the heart, digestive tract, liver and kidney, infection of respiratory tract within 4weeks prior to the challenges, pregnancy and current treatment with beta receptor blocker)were left out of the study.After the ensurance that the patient is in a stable clinical condition(by spirometery), oral aspirin challenge test is done in 2 Consecutively days.in every day 3 increasing doses of aspirin(20-40-80 & 120-160-325) will be given to the patient and the patient's clinical symptoms check.On the basis of the clinical symptoms (Naso-ocular alone/Naso-ocular and a 15% or > decline in FEV1 (Classic reaction)/ Lower respiratory reaction only (FEV1 declines by >20%)/Laryngospasm with or without a, b, c /Systemic reaction: hives, flush, gastric pain, hypotension) test result will be positive or negative.

General information

Acronym

ENT-HNS

IRCT registration information

IRCT registration number: **IRCT201408191138N12**
Registration date: **2014-09-17, 1393/06/26**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2014-09-17, 1393/06/26

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences,Vice Chancellor for Research

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of frequency of aspirin hypersensitivity in people with and without nasal polyps

Public title

aspirin hypersensitivity

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:All patients with nasal polyps that including male and female and in range of 18-60 years old who referred to ENT service in Rasht, Amiralmomenin hospital and diagnosis of nasal polyps is definite for them by endoscopy or CTs if don't have contraindications for oral aspirin challenge test inclusion to our study. Those with contraindications for oral aspirin challenge test were left out of the study : 1-a history of very severe anaphylactic reaction, 2-severe disease of the heart, digestive tract, liver and kidney, 3- infection of respiratory tract within 4weeks prior to the challenges, 4-pregnancy, 5- current treatment with beta receptor blocker. Control group is healthy people that don't have nasal polyps and contraindications for oral aspirin challenge test. Exclusion criteria:If the result of test is positive.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Not randomized

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

Guilan University of medical sciences

Street address

Shahid Beheshti BL.

City

Rasht

Postal code

Approval date

2014-05-02, 1393/02/12

Ethics committee reference number

19300775302

Health conditions studied

1

Description of health condition studied

Nasal polyp

ICD-10 code

J33

ICD-10 code description

Nasal polyp

Primary outcomes

1

Description

Nasoocular symptoms alone

Timepoint

every 1 hour to 3 h after each dose of aspirin

Method of measurement

clinical inspection

2

Description

Nasoocular symptoms and a 15% or greater decline in FEV(classic reaction)

Timepoint

every 1 hour to 3 h after each dose of aspirin

Method of measurement

clinical inspection and physical exam

3

Description

Lower respiratory reaction only (FEV1 declines by >20%)

Timepoint

every 1 hour to 3 h after each dose of aspirin

Method of measurement

clinical inspection and physical exam

4

Description

Laryngospasm with or without any of the first 3 reactions

Timepoint

every 1 hour to 3 h after each dose of aspirin

Method of measurement

clinical inspection and physical exam

5

Description

Systemic reactions: hives, flushing, gastric pain, hypotension

Timepoint

every 1 hour to 3 h after each dose of aspirin

Method of measurement

clinical inspection and physical exam

Secondary outcomes

empty

Intervention groups

1

Description
In both group oral aspirin challenge test is done. On the first day,aspirin with exponentially increasing doses (20,40,80mg),are administered at 3-hour intervals and On the second day,aspirin with exponentially increasing doses (120,160,325mg),are administered at 3-hour intervals.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin Hospital
Full name of responsible person
Dr Shadman Nemati
Street address
Amiralmomenin Hospital
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences,Vice Chancellor for Research
Full name of responsible person
Susan Komaii
Street address
Siadati st.
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan University of Medical Sciences,Vice Chancellor for Research
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
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Email
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Web page address

Person responsible for updating data

Contact

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