Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical and biochemical Aspirin desensitization effectiveness assay in patients with nasal polyposis and aspirin sensitive asthma

Protocol summary

Summary

(1) Objectives:This study is assign to investigate efficacy of aspirin desensitization in chronic rhinosinusitis with nasal polyposis patients who have aspirin sensitive asthma. (2) Design (study groups and phase, sample size, blinding, randomization, single or multi center): Nasal polyposis patients that have aspirin sensitivity in aspirin challenge test will be divided into case and control groups, seventeen in each group by third person with previous blindly randomized blocked groups setting.This is a multi central double blind study. (3) Setting and conduct: Nasal polyposis patients with aspirin sensitivity in case group will desensetize with aspirin in 2 days and receive aspirin in one month and patients in control group receive placebo. Outcome variables will be compare at the end of month one. (4) Participants including major eligibility criteria: inclusion criteria is chronic rhinosinusitis with nasal polyposis and exclusion criteria include: gasterointestinal or hematologic problem; pregnancy and immediate reactions to analgesics. (5) Intervention: Aspirin challenge test; Aspirin desensitization; Placebo in control group (6) main outcome measures: primary outcomes are quality of life and spirometry and secondary outcome variables are interleukine 4 and 5.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070728821N1**
Registration date: **2016-08-24, 1395/06/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name
negar mortazavi mehdiabad
Name of organization / entity
school of pharmacy, shahid beheshti universty of medical sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid beheshti University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and biochemical Aspirin desensitization effectiveness assay in patients with nasal polyposis and aspirin sensitive asthma

Public title

Efficacy of aspirin desensitization in nasal polyposis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: chronic rhinosinusitis (CRS) with nasal polyposis patients more than 18 years old that is

admitted in allergy clinic. CRS diagnose criteria:(1) 2 or more of symptoms: nasal congestion; pain or pressure of face; post or anterior discharge; loss of smell. (2) Symptoms should stay more than 12 week. CRS with nasal polyposis diagnose will confirm by CT SCAN or endoscopy of sinus. Exclusion criteria: Forced expiratory volume at first second less than 70% in spirometry; gastrointestinal bleeding; pregnancy or breast feeding; Anaphylaxy to Nonsteroidal anti inflammatory drugs (NSAID); Myocardial infarction or stroke in last 6 month and sever liver or kidney disease.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Blocking

Secondary Ids

1

Registry name
No

Secondary trial Id
No

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
vali asr Ave, niayesh St, Pharmacy college, Tehran, Iran

City
Tehran

Postal code

Approval date
2016-02-20, 1394/12/01

Ethics committee reference number
IR.SBMU.PHNM.1394.296

Health conditions studied

1

Description of health condition studied
nasal polyp

ICD-10 code
j33.0

ICD-10 code description
Polyp of nasal cavity

Primary outcomes

1

Description
Quality of life

Timepoint
Before and one month after intervention

Method of measurement
Questiner

2

Description
Respiratory function

Timepoint
Before and one month after intervention

Method of measurement
Spirometry

Secondary outcomes

1

Description
Interleukin 4

Timepoint
Before and onemonth after intervention

Method of measurement
Quantitative pg/ml

2

Description
Interleukin 5

Timepoint
Before and onemonth after intervention

Method of measurement
Quantitative pg/ml

Intervention groups

1

Description
Intervention group : Aspirin sensitive nasal polyposis patients will recieve 2 days desensitization protocol in

case group, that will be done by Ketrolac nasal drop (1 and 2 drop in each canal with 30 minute interval) and after that 40 and 60 mg aspirin feeding in day one and 80,160 and 325 mg aspirin in day 2, all with 90 minute interval. After desensitization 650 mg aspirin per day start in first month.

Category

Treatment - Drugs

2

Description

Control group: Aspirin sensitive patients in control group receive starch tablet instead of aspirin.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman hospital

Full name of responsible person

Negar Mortazavi Mehdiabad- Resident of Clinical Pharmacy

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Emam reza clinic

Full name of responsible person

negar mortazavi mehdiabad- resident of clinical pharmacy

Street address

Emam reza clinic, Zand Street, Shiraz, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Aarabi Ave, Yaman Street, Chamran Highway, Shahid Beheshti University of Medical University

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, Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences; School of Pharmacy

Full name of responsible person

Negar Mortazavi Mehdiabad

Position

Resident of Clinical Pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences, School of Pharmacy

Full name of responsible person

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Position

Associated prof of clinical pharmacy

Other areas of specialty/work

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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