

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Efficacy of Verapamil in patients with chronic rhinosinusitis with nasal polyposis referred to Hazrat Rasool hospital: Double blind placebo control trial

Protocol summary

Study aim

Potential morbidity of steroids in chronic rhinosinusitis with nasal polyposis (CRSwNP) treatment induces researches to alternative treatments with the same clinical efficacy but with at least side effects that is needed enough information about CRSwNP pathophysiology, diagnostic biomarkers and targeted therapies. P-gp is a new biomarker and plays an important role in CRSwNP pathogenesis. P-gp suppression is a new strategy in treatment of disease. Verapamil is P-gp suppressor and suppresses P-gp in sinonasal epithelial cells. Low doses Verapamil are tolerated by healthy patients with cluster headache, that will be prescribed in addition to routine treatment for 3 months. Results of research will be measured based on subjective and objective findings. Different studies have shown Verapamil efficacy in CRSwNP treatment with no side effects. The goal of this research is confirming efficacy, safety and novelty of Verapamil in CRSwNP treatment.

Design

Randomized, double blind, placebo control trial in 2 equal groups with 18 ones for 3 months

Settings and conduct

Low doses are tolerated by healthy patients with cluster headache. Oral Verapamil (80 mg, 3 times a day) and placebo has the same characteristics. Randomization is based on Random allocation software. Primary outcome measure is SNOT-22 questionnaire. Secondary outcome measure is (Lund-McKey score) LMS. Evaluations are done in beginning and after 12 weeks.

Participants/Inclusion and exclusion criteria

Patients referred to hospital with CRSwNP between 18-55. Patients with certain comorbidities, drugs and conductive heart disease HR<60 or SBP<110 or DBP<70

Intervention groups

groups receiving Verapamil and placebo

Main outcome variables

Age, Sex, BMI, Prior sinus surgery, concomitant Asthma, NSAID allergy, smoking, SNOT-22 score, serum total IgE, Eosinophilia in blood and nasal secretions, Odor level, LMS score

General information

Reason for update

Acronym

CRSwNP

IRCT registration information

IRCT registration number: **IRCT20191014045107N1**

Registration date: **2019-12-09, 1398/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-09, 1398/09/18**

Update count: **0**

Registration date

2019-12-09, 1398/09/18

Registrant information

Name

Afshin Rezaeifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 4933

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of Verapamil in patients with chronic rhinosinosis with nasal polypsis reffered to Hazrat Rasool hospital: Double blind placebo control trial

Public title
Efficacy of Verapamil in patients with chronic rhinosinosis with nasal polypsis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients of Male And Female reffered to Allergy and Clinical Immunology Department of Hazrat e Rasool Center Age between 18-55 years old Diagnosed with Chronic Rhinosinusitis with Nasal Polyps according to the EPOS 2012 consensus criteria; Moderate to Severe (Baseline SNOT-22 Score ≥ 20)
Exclusion criteria:
 Patients with the following comorbidities: GI Hypomotility, Heart Failure, Liver Failure, Kidney Disease, Muscular Dystrophy, Pregnant or Nursing Females, Hypertrophic Cardiomyopathy, Atrial and ventricular arrhythmia Patients with conductive heart disease like block grade 2 or 3 in EKG Patients taking the following medications; Aspirin, Beta-blockers, Cimetidine, Clarithromycin, Erythromycin, Cyclosporin, Digoxin, Disopyramide, Diuretics, Flecainide, HIV Protease Inhibitors(Indinavir, Nelfinavir, Ritonavir), Quinidine, Lithium, Pioglitazone, Rifampin and systemic corticosteroids one month before trial HR<60 or SBP<110 or DBP<70

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
 Target sample size: **36**
 More than 1 sample in each individual
 Number of samples in each individual: **18**
 18 ones in Verapamil group and 18 ones in Placebo control group

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is based on ZIP code and Random

allocation software

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients randomly are divided two equal double blind groups that receiving verapamil, INS, irrigation or irrigation, INS, Placebo .This study is randomized double placebo control trial and the third person gives Drug and Placebo to patients equally.

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of IRAN University of Medical Sciences

Street address

Hazrat E Rasool Hospital, Niayesh Ave., Sattarkhan Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.IUMS.FMD.REC.1398.291

Health conditions studied

1

Description of health condition studied

Chronic Rhinosinusitis With polyoposis, Verapamil

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Efficacy of Verapamil in treatment of patients with CRSwNP based on SNOT-22 questionnaire score

Timepoint

SNOT-22 questionnaire completion in beginning and after 12 weeks of study

Method of measurement

SNOT-22 questionnaire validated in Farsi

Secondary outcomes

1

Description

Efficacy of Verapamil in treatment of CRSwNP based on Lund - Mc Key score in sinonasal computer tomography scan

Timepoint

Measurement of LMS score in beginning and after 12 weeks of study

Method of measurement

Lund - Mc Key score in sinonasal computer tomography scan by 2 unrelated specialist

Intervention groups

1

Description

Intervention group: Receiving Verapamil Patients randomly are divided in 18 equal double - blind placebo control in 2 groups . Group 1 receive Verapamil plus Intranasal mometasone plus Nasal irrigation and Group 2 receive Placebo plus Intranasal mometasone plus Nasal irrigation. Minimum dose Verapamil use based on safety dose in Cluster headache that is defined Tab Verapamil 80 mg TDS . This study will do for 3 months. Placebo has the same characteristic of Tab Verapamil (Size, Color, Teste). Drug and Placebo are produced in Alborz daroo pharmaceutical company. FDA approved Intranasal corticosteroid is mometasone. Randomization is based on ZIP code and Random allocation software.

Category

Treatment - Drugs

2

Description

control group: Receiving Placebo Patients randomly are divided in 18 equal double - blind placebo control in 2 groups . Group 1 receive Verapamil plus Intranasal mometasone plus Nasal irrigation and Group 2 receive Placebo plus Intranasal mometasone plus Nasal irrigation. Minimum dose Verapamil use based on safety dose in Cluster headache that is defined Tab Verapamil 80 mg TDS . This study will do for 3 months. Placebo has the same characteristic of Tab Verapamil (Size, Color, Teste). Drug and Placebo are produced in Alborz daroo pharmaceutical company. FDA approved Intranasal corticosteroid is mometasone. Randomization is based on ZIP code and Random allocation software.number and Random allocation software.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat E Rasool hospital

Full name of responsible person

Mohammad Nabavi

Street address

Hazrat e Rasool hospital, Niayesh Ave., Sattarkhan Ave., Tehran

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mnabavi44@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seied Abbas Motavalian

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Iran medical university, Hemat Boul., Tehran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Nabavi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Others

Street address

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Iran University of Medical Sciences

Full name of responsible person

Afshin Rezaeifar

Position

Subspecialty Resident

Latest degree

Specialist

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

Others

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Person responsible for updating data

Contact**Name of organization / entity**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is acceptable after unidentifying people.

When the data will become available and for how long

Beginning period of acceptance is 6 months after printing of results.

To whom data/document is available

Data is acceptable only researchers who are working in academic and scientific centers

Under which criteria data/document could be used

Use of data is allowed for research applications.

From where data/document is obtainable

Receiving of documents will done by E-mail address.

What processes are involved for a request to access data/document

Receiving of documents will done by E-mail address in one month.

Comments