Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Efficacy of Verapamil in patients with chronic rhinosinositis with nasal polyposis reffered 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 strateghy 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 routin 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 contol 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, concommitant Asthm, 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)

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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 rhinosinositis with nasal polyposis reffered to Hazrat Rasool hospital: Double blind placebo control trial

Public title

Efficacy of Verapamil in patients with chronic rhinosinositis with nasal polyposis

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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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