Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Omalizumab Efficacy in Chronic Rhinosinusitis Patients with Recurrent and Refractory Nasal Polyps, Randomized Clinical trial

Protocol summary

Study aim
Evaluating the effect of amalizumab in patients with chronic rhinosinusitis and recurrent polyps

Design
The clinical trial has a control group with parallel, randomized groups, phase 3 on at least 30 referring patients, randomization is done with the rand function of Excel software.

Settings and conduct
The intervention group, treated with amalizumab, according to the standard protocol, will be placed in the allergy clinic on a monthly basis, and the control group will continue their previous medical treatments, and for both groups, the SNOT 22 questionnaire will be completed in 0-16-8-4-24 weeks. It turns out that lower scores indicate better disease control and higher quality of life in these people

Participants/Inclusion and exclusion criteria
Patients aged 18-60 with chronic rhinosinusitis and recurrent and resistant nasal polyps with a SNOT-22 score of 20 or higher were included in the study. Patients with other sinus or pulmonary disorders (except asthma), and known allergy to omalizumab were excluded from the study.

Intervention groups
The intervention group will be treated with the standard treatment protocol of Amalizumab, and the control group will continue the routine medical treatment related to the underlying disease, and for both groups, the SNOT22 questionnaire will be 0-16-8-4-0 in week 24.

Main outcome variables
Improvment the quality of life of patients treated with Omalizumab according to the SNOT22 Questionaire- Improvment of the Total Nasal Score, Nasal Congestion Score and the Degree of Smell -- improvement of lung function test in patients with history of moderate to severe asthma

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220218054057N1**
Registration date: **2023-01-24, 1401/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-24, 1401/11/04**
Update count: **0**

Registration date
2023-01-24, 1401/11/04

Registrant information

Name
rafat noeiaghdam

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3232 5500

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-10, 1401/10/20

Expected recruitment end date
2023-04-09, 1402/01/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Omalizumab Efficacy in Chronic Rhinosinusitis Patients with Recurrent and Refractory Nasal Polyps, Randomized Clinical trial

Public title

Omalizumab Efficacy in Chronic Rhinosinusitis Patients with Recurrent Nasal Polyp

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Investigation in Namazi Hospital Immunology -Allergy Clinic Complete the informed consent form Patients aged 18-75 years Usage of intranasal corticosteroid Nasal Polyp score 2 or more Total Congestion Nasal score 2 or higher SNOT22 score 20 or higher on arrival

Exclusion criteria:

The patients with other sinunasal or pulmonary disorders (except asthma) History of past or current malignancy History of a cardiac condition, hepatitis or liver cirrhosis History of recent or current infection requiring hospitalization History of recent use of immunosuppressant and biologics History of recent nasal surgery (<6 months). known allergy to omalizumab

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

One method of randomization is to use theRANDBETWEEN function in Excel. This function allows us to generate randomnumbers. To generate a random number in this study with a sample size of 30,between the two numbers 1 and 31, the function = Randbetween (1,31) is used. Thisfunction creates a column of random numbers between 1 and 31. The rand functionselects numbers with equal probability in this interval, so the chance of selecting anynumber in this interval is equal to the other numbers. This means that each patient isassigned to enter one of two treatments, respectively. These data are 30 people whoare randomly assigned to 2 treatments 1 and 2 (15 people in each group). The samplenumbers in the first group and the second are as follows:A: 15,7,6,29,23,13,10,25,12,1,4,17,26,20,11B: 28,14,21,3,8,22,2,5,16,30,27,19,18,9,24A or B could be contributed to both control and Omalizumab group.The researcher who reviews the results is not aware of the group allocation

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Science

Street address

Namazi square ,Namazi hospital

City

Shiraz

Province

Fars

Postal code

71936113311

Approval date

2022-07-02, 1401/04/11

Ethics committee reference number

IR.SUMS.MED.REC.1401.314

Health conditions studied

1

Description of health condition studied

Efficacy of omalizumab in patients with Chronic rhino sinusitis and refractory nasal polyp

ICD-10 code

ICD-10 code description

Disease of respiratory disease

Primary outcomes

1

Description

Sini nasal outcome test -22

Timepoint

Day 1; and at Weeks 4, 8, 16, and 24

Method of measurement

Point range, 0-110,lower scores indicating better disease control and quality of life . The questionnaire includes 22 variables , and the severity of each item ranges from no symptoms with a score of 0 to very severe with a score of 5. Variables include the need to fan - Sneezing - Runny nose - Cough - Discharg from the back of the throat - Thick nasal discharge - Feeling full in the ears - Dizzness - Feeling pain with pressure in the ear - Feeling pain with pressure in the face - Hard sleep - Waking up in a dream Nocturnal - Lack of good night sleep - Laziness after waking up - Fatigue during the day - Low efficiency - Low concentration - Frustration and irritability - Sad - Embarrassed - Affected sense of taste or smell and blocked and stuffy nose

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group includes the patient group that is treated with the drug Amalizumab, which is a 150 mg recombinant anti-human IgE compound manufactured by Novartis. The drug dose is defined according to the patient's weight and IgE level according to the standard table and is injected subcutaneously every 2-4 weeks for 6 months. The patient is given the necessary training about anaphylaxis. According to the prescribed drug protocol, in the IgE range of 30-100, in the weight of 30-40k, it is 75mg, in 40-90k, in the amount of 150mg, and above 90k, in the amount of 300mg. In IgE100-200, in the weight of 30-40k, in the amount of 150mg. It is 300mg in 40-80k, 450mg in 120-90k and 600mg in 125-150k. In IgE range 200-300, in 30-40k it is 225mg and in 60-40k it is 300mg and in 60- 90k is 450mg, and above 90k is 600mg. In the IgE range of 300-400 in weight 30-40k it is 300mg, in 70-40k it is 450mg and in weight above 70 it is 600mg. IgE in the range of 400-500 is 450 mg in weight 50-30 and 600 mg in weight above 50k. In IgE above 500 in weight 50-30 it is 450 mg and in weight above 40k is 600 mg.

Category

Treatment - Drugs

2

Description

Control group: Group two of chronic rhinosinusitis patients with recurrent and resistant nasal polyps treated with standard medical drugs in which there was no intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy clinic if namazi hospital

Full name of responsible person

Rafat Noeiaghdam

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Namazi Square. Namazi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad heshem Hashempoor

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Zand Street,next to Red Crescent, central building of Shiraz University of Medical Sciences ,7th floor

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Vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

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

Shiraz University of Medical Sciences

Full name of responsible person

Rafat Noeiaghdam

Position

Fellowship of Specialist in Immunology ,Asthma and Allergies

Latest degree

Specialist

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

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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
The data includes the demographic characteristics, and the process of scoring the symptoms, prick test and pulmonary function test of the patients. All the potential data can be shared after de-identifying the people.
When the data will become available and for how long
Access starts 6 months after the results are published
To whom data/document is available
Researchers of academic institutions
Under which criteria data/document could be used
All data can be published if used to improve the treatment of patients under ethical principles.
From where data/document is obtainable
Rafat Noeiaghdam - Shiraz, Namazi Hospital, Department of Immunology and Allergy - rafatnoi@sums.ac.ir-09171153977
What processes are involved for a request to access data/document
After sending the application, if the research process is approved from the scientific and ethical point of view by the research vice-chancellor of Shiraz University of Medical Sciences, the data will be sent within a week.
Comments