Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Study of the effect of omalizumab on the recurrence of polyposis in patients with allergic fungal sinusitis who underwent surgery

Protocol summary

Study aim

The study objectives include determining the effect of omalizumab on nasal polyposis recurrence, nasal-related quality of life, and symptom severity after surgery.

Design

A controlled, double-blind, randomized, phase 2-3 clinical trial with parallel groups on 36 patients. The rand function of Excel software will be used for randomization.

Settings and conduct

This study will be conducted in the ENT Department of Besat Hospital, Hamadan, on patients with allergic fungal sinusitis who will undergo endoscopic sinus surgery. For blinding, both omalizumab and placebo will be prepared by injection using identical syringes by a nurse who is not involved in the study and is unaware of the type of drug. The physician who will perform the endoscopic evaluations and the person who will perform the statistical analyses will also be unaware of the groups until the end of the analysis (double-blind).

Participants/Inclusion and exclusion criteria

Patients with a diagnosis of allergic fungal rhinosinusitis who will undergo endoscopic sinus surgery.

Intervention groups

Both groups will receive standard postoperative treatment regimen (including nasal irrigation with saline, mucolytic drugs, and topical corticosteroids). The intervention group will receive subcutaneous omalizumab injection at a dose of 0.016 mg/kg for 2 months in addition to standard treatment. Control group: Will receive placebo (injectable vitamin B complex) instead of omalizumab.

Main outcome variables

The primary outcome of this study is the frequency of nasal polyp recurrence. This outcome will be measured at four time points: one month, two months, three months, and six months after the intervention: The Lund-Kendy score grades the pathological conditions visible on nasal endoscopy, including polyps, discharge, edema, scarring, and scaling, with higher scores indicating greater disease severity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N52**
Registration date: **2026-03-09, 1404/12/18**
Registration timing: **prospective**

Last update: **2026-03-09, 1404/12/18**
Update count: **0**

Registration date

2026-03-09, 1404/12/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2026-08-22, 1405/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study of the effect of omalizumab on the recurrence of polyposis in patients with allergic fungal sinusitis who underwent surgery

Public title
Omalizumab in Polyp Recurrence Prevention
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of primary or recurrent Allergic Fungal Rhinosinusitis Informed consent to participate in the study Age 18 to 60 years
Exclusion criteria:
Contraindication to omalizumab Diagnosis of secondary rhinosinusitis (due to immunodeficiency, genetic disorders, etc)
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization with 4-patient blocks
Blinding (investigator's opinion)
Double blinded
Blinding description
Outcome assessor and data analyst are blinded to group allocation
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan Univercity of Medical Science
Street address
Shahid Fahmideh
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Province
Hamadan
Postal code
6517838697
Approval date
2026-02-14, 1404/11/25
Ethics committee reference number
IR.UMSHA.REC.1404.959

Health conditions studied

1

Description of health condition studied
Allergic fungal sinusitis
ICD-10 code
J01
ICD-10 code description
Acute sinusitis

Primary outcomes

1

Description
Recurrence of sinusitis
Timepoint
1, 2, 3 and 6 months after the start of the intervention
Method of measurement
Sinus anoscopy

2

Description
Severity of nasal symptoms (nasal congestion, nasal discharge, sneezing, headache, snoring, and decreased sense of smell)
Timepoint
1, 2, 3 and 6 months after the start of the intervention
Method of measurement
With 10-degree visual analog scale (VAS)

Secondary outcomes

1

Description
Quality of life related to sinusitis
Timepoint
1, 2, 3 and 6 months after the start of the intervention
Method of measurement
Assessment with the SNOT-22 scale

Intervention groups

1

Description
Intervention group: In addition to the standard routine

treatment regimen (serum lavage, mucolytics, and topical corticosteroids), omalizumab treatment was initiated at a dose of 0.016 mg/kg per injection based on the existing protocol and continued for 2 months.

Category

Treatment - Drugs

2

Description

Control group: They will receive only the standard routine treatment regimen (serum lavage, mucolytics, and topical corticosteroids) and placebo (injectable vitamins B1 and B6 (B complex).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital

Full name of responsible person
dr Javane Jahanshahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences

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Abbas Moradi

Position
MSc in epidemiology/ Comunity Medicine MS

Latest degree
Master

Other areas of specialty/work
Epidemiology

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data can be shared except for authors names
When the data will become available and for how long
From 2027 onwards it is permissible
To whom data/document is available
Clinical professionals and Researchers in all fields
Under which criteria data/document could be used
For treatment and develop research and science
From where data/document is obtainable
Correspond to the email address of the scientific responsible for the study
What processes are involved for a request to access data/document
Send and receive email
Comments