

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 randomization 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-Kenny 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

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

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Iran (Islamic Republic of)

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Recruitment status

recruiting

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 University of Medical Science

Street address

Shahid Fahmideh

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Hamadan

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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**

Hamedan University of Medical Sciences

Full name of responsible person

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Web page address**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

Full name of responsible person

Abbas Moradi

Position

MSc in epidemiology/ Community Medicine MS

Latest degree

Master

Other areas of specialty/work

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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