Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A placebo-controlled double-blind randomized trial of itraconazole for Allergic Fungal Sinusitis

Protocol summary

Summary

The purpose of this randomized double- blind controlled study is to determine the efficacy of itraconazole in the treatment of patients with Allergic Fungal Sinusitis (AFS). These patients, after endoscopic sinus surgery and routine therapy consisting of prednisolone (1mg/kg body weight for a period of ten days), nasal spray corticosteroid and Amphotericin (100 mg/ml) in distilled water for nasal irrigation will be divided in two groups. The control group will receive placebo and intervention group Itraconazole (200 mg daily) for two months after surgery. Patients with a history of prior sinus surgery, systemic disease, pregnant or lactating women are excluded from this study. A total of 36 patients between 15 and 65 years old who suffer from AFS in Khuzestan will be enrolled. At the end of the 3rd month diagnostic nasal endoscopy and CT scan will be done and the patients will fill a questionnaire of quality of life (Snot 20).

General information

Acronym

Allergic Fungal Sinusitis (AFS)

IRCT registration information

IRCT registration number: **IRCT201204049375N1**
Registration date: **2013-04-09, 1392/01/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-09, 1392/01/20

Registrant information

Name

Soheila Nikakhlagh

Name of organization / entity

Ahvaz Jondishapoor University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research affairs, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2013-06-20, 1392/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A placebo-controlled double-blind randomized trial of itraconazole for Allergic Fungal Sinusitis

Public title

The effect of itraconazole in the treatment of allergic fungal sinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with diagnosis of allergic fungal sinusitis based on culture and pathology.
Exclusion criteria: history of previous sinus surgery, history of systemic disease, pregnant or nursing mother, patient who display rising of hepatic enzymes during treatment with itraconazole.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

College Town, Golestan

City

Ahvaz

Postal code

6135715794

Approval date

2011-12-27, 1390/10/06

Ethics committee reference number

314

Health conditions studied

1

Description of health condition studied

fungal sinusitis

ICD-10 code

J32

ICD-10 code description

chronic sinusitis

Primary outcomes

1

Description

Therapeutic effect of Itraconazol on fungal sinusitis

Timepoint

three months after intervention

Method of measurement

Endoscopic and CT scan findings

Secondary outcomes

1

Description

quality of life

Timepoint

three months after intervention

Method of measurement

Snot-20 questionnaire

Intervention groups

1

Description

Intervention: Prednisolone 1mg/kg for 10 days followed by nasal corticosteroid and topical irrigation with amphotericin plus itraconazole 200 mg daily for two months

Category

Treatment - Drugs

2

Description

Control group: Prednisolone 1 mg/kg for 10 days followed by nasal corticosteroid and topical irrigation with amphotericin plus placebo daily for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Soheila Nikakhlagh

Street address

Otolaryngology Department, Imam Khomeini Hospital, Azadegan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhi

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Vice chancellor for research affairs , College town , Golestan
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Ahvaz
Grant name
معاونت پژوهشی
Grant code / Reference number
u-90204
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapour University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty