

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effectiveness of Itraconazole on clinical symptoms and radiologic findings in patients with recurrent chronic rhinosinusitis and nasal polyposis

Protocol summary

Summary

At the start of the study demographic data, clinical symptoms (severity of rhinorrhea, nasal obstruction, hyposmia, dyspnea), quality of life (by SNOT-20), serum IgE, Score of CT scan (by Lund-Mackay) were recorded. Severity of rhinorrhea, nasal obstruction, hyposmia, dyspnea was asked from the patients by the score of none, mild, moderate and severe. Itraconazole capsule of 100 mg, twice per day prescribed for 3 months. (Rose Daru- Tehran- Iran). Patients were followed in the first month for clinical symptoms, and then at the 3rd and 6th months regarding to clinical symptoms, quality of life (by SNOT-20), serum IgE, Score of CT scan (by Lund-Mackay). At the 6th month, patients were evaluated for clinical symptoms again. Liver Enzyme tests and side effects were evaluated monthly. At the end of the study, data were analyzed by SPSS version 20 by Friedman analysis, T-test, Spearman's and Wilcoxon tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211062106N4**

Registration date: **2013-02-25, 1391/12/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-25, 1391/12/07

Registrant information

Name

Afroz Eshaghian

Name of organization / entity

Isfahan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-11-01, 1390/08/10

Expected recruitment end date

2012-12-01, 1391/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Itraconazole on clinical symptoms and radiologic findings in patients with recurrent chronic rhinosinusitis and nasal polyposis

Public title

Itraconazole and clinical and radiologic findings in patients with recurrent chronic rhinosinusitis and nasal polyposis

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria contained patients at least 15 years old without history of hepatic disease and heart failure; without allergy to Itraconazole, and usage of interacting medications (cisapride, dofetilide, ergot derivatives, levomefentanyl, lovastatin, midazolam (oral), nisoldipine, pimozide, quinidine, simvastatin, or triazolam). Exclusion criteria of the study were no compliance for follow up; side effects of Itraconazole like rising in hepatic enzyme;

nausea, vomiting or starting a new treatment during the study.

Age

From **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical sciences, Vice Challenry

Street address

Hezar Jarib St, Isfahan

City

Isfahan

Postal code

جمهوری اسلامی ایران

Approval date

2011-11-01, 1390/08/10

Ethics committee reference number

390393

Health conditions studied

1

Description of health condition studied

nasal polyposis

ICD-10 code

J33

ICD-10 code description

Nasal polyp

2

Description of health condition studied

Chronic rhinitis

ICD-10 code

J32

ICD-10 code description

Chronic rhinitis

Primary outcomes

1

Description

Severity of rhinorrhea, nasal obstruction, hyposmia, dyspnea

Timepoint

0, 1st, 3rd and 6th months

Method of measurement

Asking the patient about the score of none, mild, moderate and severe

Secondary outcomes

1

Description

Quality of life

Timepoint

0,1st, 3rd and 6th months

Method of measurement

SNOT-20

2

Description

Serum IgE

Timepoint

0 and 3rd months

Method of measurement

Unit

3

Description

Score of CT scan

Timepoint

0 and 3rd months

Method of measurement

Lund-Mackay scale

4

Description

Side effects like elevated liver enzyme, diarrhea and nausea

Timepoint

0,1st, 3rd and 6th months

Method of measurement

Ask a patient

Intervention groups

1

Description

Itraconazole capsule of 100 mg, twice per day prescribed

for 3 months.(Rose Daru- Tehran- Iran).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Street address

City

Isfahan

2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, Vice Challenry

Full name of responsible person

Dr Peyman Adibi

Street address

Isfahan University of Medical Sciences, Hezar jarib St.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences, Vice Challenry

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

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Akram Fereidani

Position

MD, Resident of Otolaryngology

Other areas of specialty/work

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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