Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 was 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 Wilcaxon 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

Afrooz 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, levomethadyl 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