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: 0
Registration date 2013-02-25, 1391/12/07

Registrant information
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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

Secondary 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
مهندسی 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

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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty