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
Afrozeh Eshaghian
Name of organization / entity
Isfahan university of medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 1236 7247
Email address
eshaghian@edc.mui.ac.ir

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, doxetilide, 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 rhinorrea, 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

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Street address</th>
<th>City</th>
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<tbody>
<tr>
<td>1</td>
<td>Isfahan University of Medical Sciences, Vice Chancellor</td>
<td>Dr Peyman Adibi</td>
<td>Isfahan University of Medical Sciences, Hezar jarib St.</td>
<td>Isfahan</td>
</tr>
</tbody>
</table>

#### Person responsible for scientific inquiries
- **Name of organization / entity** Isfahan University of Medical Sciences
- **Full name of responsible person** Mostafa Hashemi
- **Position** MD, Resident of otolaryngology; Otolaryngologist
- **Other areas of specialty/work**
- **Street address** Kashani hospital, Kashani St.
- **City** Isfahan

#### Person responsible for updating data
- **Name of organization / entity** Isfahan University of Medical Sciences
- **Full name of responsible person** Afrooz Eshaghian
- **Position** MD, Resident of Otolaryngology
- **Other areas of specialty/work**
- **Street address** Al-Zahra hospital, Sofe St.
- **City** Isfahan

### Person responsible for general inquiries
- **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**
- **Street address** Al-Zahra hospital, Sofe St.
- **City** Isfahan

### Sharing plan
- **Deidentified Individual Participant Data Set (IPD)**
- **Study Protocol**
- **Statistical Analysis Plan**
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty