Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparative study of the effectiveness of "Intraconazole with fluticasone", "Doxycycline with fluticasone", and "Fluticasone spray alone" in the treatment of chronic rhinosinusitis with nasal polyp

Protocol summary

Study aim
Determining and comparing the effectiveness of "Intraconazole with fluticasone", "Doxycycline with fluticasone", and "Fluticasone spray alone" in the treatment of chronic rhinosinusitis with nasal polyps

Design
The randomized, Single-blind clinical trial, with the parallel groups, Phase 2 on 108 patients

Settings and conduct
In this randomized Single-blind clinical trial study, 108 eligible patients referred to Kashani and Al-Zahra hospitals in Isfahan will be included in the study and randomly divided into 3 groups. Patients in the first group will be prescribed itraconazole with fluticasone, in the second group "doxycycline with fluticasone", and in the third group "fluticasone spray alone", then the symptoms of chronic rhinosinusitis will be compared between the three groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include age 15-65 years, with chronic rhinosinusitis, more than 6 months of chronic rhinosinusitis, no medication to control chronic rhinosinusitis in a recent month, and consent to participate in the study. Exclusion criteria include diabetes, endocrine-metabolic diseases, immunodeficiency diseases, allergy to the studied drugs, and the incidence of hepatic complications due to using intraconazole.

Intervention groups
Intervention group 1: Patients in this group will receive doxycycline 100 mg twice a day, along with flomist spray intranasally (one puff per nostril every 12 hours). Intervention group 2: Patients in this group will receive only flomist spray intranasally (one puff per nostril every 12 hours). Intervention group 3: Patients in this group will receive two capsules of itraconazole 100 mg daily in divided doses, along with flomist spray intranasally (one puff in each nostril every 12 hours).

Main outcome variables
Symptoms of chronic rhinosinusitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N50**
Registration date: **2021-12-26, 1400/10/05**
Registration timing: **prospective**

Last update: **2021-12-26, 1400/10/05**
Update count: **0**

Registration date
2021-12-26, 1400/10/05

Registrant information
Name
Asieh Maghami Mehr
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-04-20, 1401/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effectiveness of "Intraconazole with fluticasone", "Doxycycline with fluticasone", and "Fluticasone spray alone" in the treatment of chronic rhinosinusitis with nasal polyp

Public title
Comparative study of the effectiveness of "Intraconazole with fluticasone", "Doxycycline with fluticasone", and "Fluticasone spray alone" in the treatment of chronic rhinosinusitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 65-15 years Having chronic rhinosinusitis More than 6 months history of chronic rhinosinusitis Do not take medication to control chronic rhinosinusitis in a recent month Satisfaction to participate in the study
Exclusion criteria:
Having diabetes Having endocrine and metabolic diseases Having Immune deficiency diseases Allergy to the studied drugs Incidence of hepatic complications due to intraconazole
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 108 eligible patients are randomly selected. For this, the letter A is written on 36sheets, the letter B is written on 36 sheets, and the letter C is written on 36sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of three groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the variety of treatment interventions, the specialist physician is aware of the prescription of each medication. But patients will not know what kind of spray, that they use. In addition, the person recording the clinical and baseline information of the patients as well as the statistical analyst will not be aware of the type of intervention
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2020-11-10, 1399/08/20
Ethics committee reference number
IR.MUI.MED.REC.1399.706

Health conditions studied

1

Description of health condition studied
Chronic rhinosinusitis
ICD-10 code
J32
ICD-10 code description
Chronic sinusitis

Primary outcomes

1

Description
Symptoms of chronic rhinosinusitis
Timepoint
Before and after the intervention
Method of measurement
Twenty-two-item Sino-Nasal Outcome Test (SNOT-22)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in this group will receive doxycycline 100 mg twice a day, along with flomist spray intranasally (one puff per nostril every 12 hours).
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in this group will receive only flomist spray intranasally (one puff per nostril every 12 hours).
Category
Treatment - Drugs

3

Description
Intervention group 3: Patients in this group will receive two capsules of itraconazole 100 mg daily in divided doses, along with flomist spray intranasally (one puff in each nostril every 12 hours).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Sayed Mostafa Hashemi
Street address
ENT Department, Kashani Hospital, Kashani Street.
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2

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Sayed Mostafa Hashemi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available