

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the therapeutic effect of fluconazol drop on chronic rhinosinusitis in patients referred to otorhinolaryngology clinic in Hamadan

Protocol summary

Summary

This research is randomized double-blind clinical trial. The patients who referred to ENT clinic and chronic rhinosinusitis (CRS) were diagnosed based on the AAO-HNS definition of CRS, randomly divided to 2 groups. One group as control, receive placebo and beclomethasone nasal spray and the intervention group receive fluconazole drop and beclomethasone nasal spray every 12 hours. The bottle of drops is coded by pharmaceutical faculty of Tehran University. Treatment courses last for 2 months. Endoscopic score and SNOT-20 instruction and CT score is recorded before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811063186N1**

Registration date: **2011-08-02, 1390/05/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-02, 1390/05/11

Registrant information

Name

Farnaz Hashemian

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3827 9001

Email address

hashemian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Science

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of fluconazol drop on chronic rhinosinusitis in patients referred to otorhinolaryngology clinic in Hamadan

Public title

Evaluation of the therapeutic effect of fluconazol drop on chronic rhinosinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the patients with diagnosis of chronic rhinosinusitis according to American Academy of Otolaryngology which have no response to medical therapy; Exclusion criteria: known sensitivity to fluconazole; pregnancy and breast feeding women; immune compromised patients; patients with acute complication of CRS; superimposition of ARS (fever, acute pain, pressure on face); antibiotic use in recent 7 days ; age below 18 years; systemic antifungal use in recent 7 days and systemic steroid use in recent 30 days

Age

No age limit

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Science

Street address

Hamedan University of Medical Sciences, shaheed Fahmideh Ave.Hamedan, Iran

City

Hamadan

Postal code

65178-3-8736

Approval date

2009-01-20, 1387/11/01

Ethics committee reference number

16/35/9/56549

Health conditions studied

1

Description of health condition studied

rhinosinusitis

ICD-10 code

(B95-B97)

ICD-10 code description

Bacterial, viral and other infectious agents

Primary outcomes

1

Description

snot-20

Timepoint

2 months

Method of measurement

Check list

2

Description

CT score

Timepoint

2 months

Method of measurement

Check list

Secondary outcomes

1

Description

Side effect

Timepoint

2 months

Method of measurement

Check list

Intervention groups

1

Description

Intervention group: drop bottles including fluconazole 2%. is used 2 times per day (4 drops) for 2 months, also beclomethasone nasal spray is used 2 times per day (2 puffs) for 2 months.

Category

Treatment - Drugs

2

Description

Control group: drop bottles with the appearance identical to intervention group, includes normal saline which is used 2 times per day, 4 drops, for 2 months. Also beclomethasone nasal spray is used 2 times per day (2 puffs) for 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

ENT clinics of Hamedan University of Medical Science

Full name of responsible person

Street address

Hamedan, Sheikholraiss clinic and Besat hospital

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Science

Full name of responsible person

Tavilani-Heydar

Street address

Shahid Fahmideh Blv, Hamedan University of Medical Science

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Science

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

Hamedan University of Medical Science

Full name of responsible person

Farnaz Hashemian

Position

Assistant professor

Other areas of specialty/work

Street address

Hamedan university of medical science-Shaheed Fahmideh Blv. Hamedan

City

Hamedan

Postal code

Phone

+98 81 1264 0039

Fax

Email

hashemianf@yahoo.com; hashemian@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Science

Full name of responsible person

Farnaz Hashemian

Position

Rhinology fellow ship

Other areas of specialty/work

Street address

Hamedan university of medical science-Shaheed Fahmideh Blv. Hamedan -Iran

City

Hamedan

Postal code

Phone

+98 81 1264 0039

Fax

Email

hashemianf@yahoo.com; hashemian@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Science

Full name of responsible person

Hashemian Farnaz

Position

Assistant professor

Other areas of specialty/work

Street address

Hamedan University of Medical Science, shahid Fahmideh Blv, Hamedan

City

Hamedan

Postal code

Phone

+98 81 1839 5403

Fax

+98 81 1826 9835

Email

hashemian@umsha.ac.ir

Web page address

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