

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of the effect of topical calcitriol on Chronic Rhinosinusitis with and without polyps

Protocol summary

Summary

Study objective: finding a better and more cost-effective way to treat chronic rhinosinusitis with and without polyposis. Study design: randomized, double-blind, placebo-controlled, single centre. Inclusion criteria: all patients older than 18 years with the diagnostic criteria for chronic rhinosinusitis with polyposis based on the EPOS 2012 criteria. Exclusion criteria: smoking; sensitivity to vitamin D3; pregnancy; use of systemic steroids in last month; immunosuppressive drugs; history of any endocrine disease; malignancy; acute rhinosininitis during study; surgery for rhinosinusitis; complication of rhinosinusitis; calcification of soft tissue and hypercalcemia. The patients divided to 2 groups by block randomization. Intervention group will receive fluticasone nasal spray (2 puffs in each nasal cavity, once a day) and calcitriol spray (2 puffs in each nasal cavity equivalent to 2,000 units of vitamin D or 50 micrograms of calcitriol, once a day) for one month, and the control group will receive fluticasone nasal spray and placebo in the same dose. VAS and SNOT-22, and endoscopic exam questionnaire will be completed before and after intervention (at the first and third month). Sample size:60. Blinding: fluticasone and placebo spray will be prepared in similar bottles and coded by pharmacist and will be delivered to the researcher; so neither researcher nor the patients will find out about the contents of the bottles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705173186N11**

Registration date: **2017-10-20, 1396/07/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-20, 1396/07/28

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 scinnce

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of topical calcitriol on Chronic Rhinosinusitis with and without polyps

Public title

Assessment of the effect of topical calcitriol on Chronic Rhinosinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients older than 18 years with the diagnostic criteria for chronic rhinosinusitis with polyposis based on the EPOS 2012 criteria. Exclusion criteria: smoking; sensitivity to vitamin D3; pregnancy; use of systemic steroids in last month; immunosuppressive drugs; history of any endocrine disease, malignancy, acute rhinosinusitis during study, surgery for rhinosinusitis, complication of rhinosinusitis, calcification of soft tissue and hypercalcemia.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 Hamedan university of medical sciences

Street address

Shahid Fahmideh Ave., Hamadan

City

Hamadan

Postal code

65178

Approval date

2017-04-08, 1396/01/19

Ethics committee reference number

IR.UMSHA.REC.1396.9

Health conditions studied**1****Description of health condition studied**

chronic rhinosinusitis with and without polyps

ICD-10 code

J32

ICD-10 code description

chronic sinusitis

Primary outcomes**1****Description**

chronic rhinosinusitis

Timepoint

Before intervention and 1and 3 months after intervention

Method of measurement

VAS, SNOT22 and Lund Kennedy scoring

Secondary outcomes**1****Description**

drug adverse effect such as nasal irritation

Timepoint

during study period

Method of measurement

questionnaire

Intervention groups**1****Description**

Intervention group: nasal spray fluticasone once a day, 2 puff in each nasal cavity with calcitriol spray once a day (equivalent 2000 unit vitamin D or 50 micro gram calcitriol) for one month

Category

Treatment - Drugs

2**Description**

control group: nasal spray fluicasone and placebo

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

hamadan besat hospital, ENT clinic

Full name of responsible person

Dr.farnaz hashemian

Street address

ENT clinic, Besat Hospital, shahid Motahari Blvd., Hamadan, Iran

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Shahid Fahmideh Ave., Hamadan University of Medical Sciences

City

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Hamadan University of Medical Sciences

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**

Hamadan University of Medical Sciences

Full name of responsible person

Farnaz Hashemian

Position

Associate professor

Other areas of specialty/work**Street address**

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Full name of responsible person

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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