Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 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 rhinosinisitis 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)
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+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 rhinosinisitis 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
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Hamadan
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
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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