Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessment of the effect of Vitamin D Supplementation on recurrence rate of nasal polyposis after endoscopic sinus surgery : A Triple Blinded Randomized Controlled Trial

Protocol summary

Summary

Patients with sinonasal polyposis that are candidates for surgery with serum levels of 10-30 ng / ml vit D3 (Insufficiency) will be enrolled and randomly (blocking technique) assigned into two groups (the control and the case) and written informed consent will be obtained. Patients with Samter's triad randomly will be distributed in both groups. Before surgery, all patients will be treated for 10 days with oral prednisolone 10 mg and cefixime 400mg per day and fluticasone spray,2 puffs each nostril, once a day. VAS & SNOT-22 questionnaire and Meltzer endoscopic grading score will be recorded . Patients undergoing endoscopic sinus surgery by one surgeon .After surgery, both groups of patients will receive routine post operative management (debridement in the first week, fluticasone spray two puffs daily, irrigation, tab cefixime 400 mg daily for 10 days and montelukast for a month).The case group will be received oral vitamin D tablets 4000 IU (single dose daily) for one month and the control group will be received placebo as the same manner. At the end of the first ,third and sixth month VAS and SNOT-22 and Meltzer endoscopic grading score will be recorded. For blinding; the pharmacist will provide the coded placebo and vit.D in same containers for the researcher, so the patients , the researcher and the statistical consultant wont be aware of the contents.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608043186N8**
Registration date: **2017-02-02, 1395/11/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-02, 1395/11/14

Registrant information

Name
Farnaz Hashemian
Name of organization / entity
Hamadan University of Medical Sciences
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Iran (Islamic Republic of)
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+98 81 3827 9001
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research ,Hamadan University of Medical Sciences

Expected recruitment start date

2016-09-20, 1395/06/30

Expected recruitment end date

2017-09-20, 1396/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Vitamin D Supplementation on recurrence rate of nasal polyposis after endoscopic sinus surgery : A Triple Blinded Randomized Controlled Trial

Public title

Effect of Vitamin D Supplementation on nasal polyp relaps

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: All patients older than 18 years with the diagnostic criteria for chronic sinusitis with polyposis based on the American Academy criteria . Exclusion criteria: Smoking; sensitivity to vitamin D3; Pregnancy; Long-term systemic steroids (greater than 10 days); immunosupressive drugs; history of any endocrine disease. Skeletal. Kidney. Gastrointestinal disease; use of estrogen drugs, thiazide diuretics, digoxin, antacids Therapy and isoniazid

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
randomization will be done by blocking technique

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
2016-09-17, 1395/06/27

Ethics committee reference number
IR.UMSHA.REC.1395.290

Health conditions studied

1

Description of health condition studied
Nasal polyposis

ICD-10 code
J33.8

ICD-10 code description
nasal polyp, unspecified

Primary outcomes

1

Description
recurrence of nasal and paranasal sinus polyp

Timepoint
Before intervention and 1, 3 and 6 months after intervention

Method of measurement
VAS,Snot 22, Meltzer grading

2

Description
Rhinosinusitis sign

Timepoint
Before intervention and 1, 3 and 6 months after intervention

Method of measurement
Meltzer endoscopic grading

Secondary outcomes

1

Description
side effects of vit D3

Timepoint
1 , 3 and 6 months after intervention

Method of measurement
questioner

Intervention groups

1

Description
Intervention group: Vitamin D Tab 4000 IU once a day for 1 month.

Category
Treatment - Drugs

2

Description
Control group : Placebo one Tab per day for 1 month

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
ENT clinic
Full name of responsible person
Dr Farnaz Hashemian
Street address
ENT clinic, Besat Hospital, shahid Motahari Blvd., Hamedan, Iran
City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
Street address
Shahid Fahmideh Ave., Hamedan University of Medical Sciences
City
Hamedan

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, Hamedan 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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Person responsible for updating data

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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