

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 won't 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

Country

Iran (Islamic Republic of)

Phone

+98 81 3827 9001

Email address

hashemian@umsha.ac.ir

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); immunosuppressive 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

Hamedan University of Medical Sciences

Full name of responsible person

Farnaz Hashemian

Position

Associate professor

Other areas of specialty/work

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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