Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of vitamin D on recurrence of chronic rhinosinusitis associated with nasal polyposis after functional endoscopic sinus surgery (Triple blind, Placebo-controlled randomized clinical trial)

Protocol summary

Study aim

Determining the effect of vitamin D on recurrence of chronic nasal sinusitis with polyposis

Design

triple blind, Placebo-controlled randomized clinical trial with control group, phase 3 on 100 patients.

Settings and conduct

The statistical population includes patients referred to Amiralam Hospital with chronic nasal sinusitis with polyposis, which are randomly divided into placebo and intervention groups. The intervention group is treated with vitamin D3 for 6 months. The control group is given a placebo. The study is triple blind and the participants, the surgeon and the statistician who performs the study analysis, are kept blind to being assigned to the study groups.

Participants/Inclusion and exclusion criteria

The statistical population includes patients referred to Amir Alam's Hospital with chronic nasal sinusitis with polyposis in the age range of 18 to 65 years. Exclusion criteria in the study include: dissatisfaction, Getting Covid-19 and taking vitamin D followed during the study, acute complications of chronic sinusitis, Immunosuppressive drug use, Contraceptive drug use (OCP), Anti TB drug use, Patients with active infection, Recent hypercalcemia or history of hypercalcemia, Anticonvulsant drug, Kidney stone, Recent tanning history, Pregnancy, Breastfeeding, history of malabsorption, vitamin D levels above 80, continuous intake of vitamin D3 supplementation of more than 400 units per day, acute exacerbation of acute bacterial sinusitis.

Intervention groups

Both control and intervention groups will be divided into three subgroups. The intervention group is then treated with vitamin D3 for 6 months. The control group is given a placebo.

Main outcome variables

The effect of vitamin D on endoscopic score of patients with nasal polyposis based on Lund Kennedy score and SNOT 22, CT scan and endoscopy results

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211026052878N1**
Registration date: **2021-12-18, 1400/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-18, 1400/09/27**
Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

Name

Shirin Irani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6670 3037

Email address

sh_irani@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2022-12-11, 1401/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin D on recurrence of chronic rhinosinusitis associated with nasal polyposis after functional endoscopic sinus surgery (Triple blind, Placebo-controlled randomized clinical trial)

Public title

The effect of vitamin D on recurrence of chronic rhinosinusitis associated with nasal polyposis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referred to Amiralam Hospital with chronic nasal sinusitis with polyposis

Exclusion criteria:

Dissatisfaction Getting Covid 19 and getting vitamin D followed while studying Patients with acute complications of chronic sinusitis Taking immunosuppressive drugs Contraceptive drug use (OCP) Taking Anti TB drugs Patients with active infection Recent hypercalcemia or history of hypercalcemia Get anticonvulsant medicine Nephrolithiasis Recent tanning history Pregnancy Breastfeeding History of malabsorption Vitamin D levels above 80 Continuous vitamin D3 supplementation over 400 units per day Acute exacerbation of acute bacterial sinusitis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked Randomization is used. Four blocks of defined intervention (A) and control (B) groups (AABB, ABAB, ABBA, BBAA, BABA, BAAB) and written on cards 1-6, the cards are placed in the envelope. The cards are then randomly selected and a random string is made from the selected card sequence. Patients in the intervention and control groups are included in the study based on this sequence.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, the surgeon, the statistician who analyzes the study are kept blind to their assignment to study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Tehran of University of Medical Sciences

Street address

Keshavarz Blvd., Ghods St., Vice Chancellor for Research and Technology, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-10-17, 1400/07/25

Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1400.034

Health conditions studied

1

Description of health condition studied

Chronic rhinosinusitis with nasal polyposis

ICD-10 code

J32.9

ICD-10 code description

Chronic sinusitis, unspecified

Primary outcomes

1

Description

Patient score in SNOT-22 questionnaire

Timepoint

One month, three months and six months after surgery

Method of measurement

The Sino-Nasal Outcome Test (SNOT-22)

2

Description

Patient score in Lund-Mackay score of CT scan

Timepoint

One month, three months and six months after surgery

Method of measurement
Lund-Mackay score of CT scan

3

Description
Patient score in Lund-Kennedy score
Timepoint
One month, three months and six months after surgery
Method of measurement
Lund-Kennedy score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with chronic rhinosinusitis associated with polyposis treated with vitamin D. Both control and intervention groups will be divided into three subgroups. The first subgroup has a vitamin D level below 20 ng / ml (deficient), the second subgroup has a vitamin D level of 20-29 ng / ml (Insufficient), the third subgroup has a vitamin D level greater than 30 ng / ml (Sufficient).The first subgroup receives 50,000 units of vitamin D eight weeks weekly and then monthly. The second subgroup receives 50,000 units of vitamin D eight weeks weekly and then monthly. The third subgroup receives 50,000 units of vitamin D per month.
Category
Treatment - Drugs

2

Description
Control group: Patients with chronic rhinosinusitis associated with polyposis treated with placebo in a similar way.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
ENT Clinic of Amir Alam Hospital
Full name of responsible person
Leyla Noury
Street address
Enghelab St., North Saadi, ENT Clinic of Amir Alam Hospital
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141765371
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leyla.noury@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Keshavarz Boulevard, Qods Street
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Leyla Noury
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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North Saadi Street, the new building of Amir Alam Hospital

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available