

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of vitamin D supplementation on prevention of recurrence of rhinosinusitis with nasal polyp after endoscopic surgery

Protocol summary

Study aim

Effect of vitamin D supplementation on prevention of recurrence of rhinosinusitis with nasal polyp after endoscopic surgery

Design

A phase 3 clinical trial with two intervention and one control groups, parallel groups, not blinded, simple randomized groups with coded card selection; sample size of 70

Settings and conduct

This clinical trial study was performed on patients referred to Kashani and Alzahra hospitals in Isfahan. Patients are given vitamin D supplements according to the protocol and, based on patient's access and preference, give the patient one vitamin D pearl (50,000 IU) once a week for 8 weeks or a 300,000 unit in 1 ml ampule monthly (intramuscular injection). We then examine individuals for relapse and quality of life after six months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing endoscopic sinus surgery due to rhinosinusitis with nasal polyp; consent to participate in the study; age ranging from 18 to 64; Exclusion criteria: Patients with allergic rhinitis; Patients with a nasal mass; Patients with a history of treatment for vitamin D, rickets, osteoporosis, osteomalacia and other metabolic bone diseases.

Intervention groups

The intervention group: they are given vitamin D supplement. Control group: they will not receive any intervention. Patients in this group will receive vitamin D supplementation after 6 months and after completing the study.

Main outcome variables

Rhinosinusitis relapse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N36**

Registration date: **2020-05-02, 1399/02/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-02, 1399/02/13**

Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name

Sadra Ansaripour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-14, 1399/01/26

Expected recruitment end date

2020-07-16, 1399/04/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on prevention of recurrence of rhinosinusitis with nasal polyp after

endoscopic surgery

Public title
The effect of vitamin D supplementation in preventing recurrence of rhinosinusitis with nasal polyps

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing endoscopic sinus surgery due to rhinosinusitis with nasal polyps. Individual consent to participate in the study Age between 18 and 64 years old
Exclusion criteria:
Patients with allergic rhinitis Patients with a nasal mass such as inverted papilloma, enterocolocular polyp, carcinoma, sarcoma, encephalosil, pyogenic granuloma and angiofibroma Patients with a history of treatment for vitamin D, rickets, osteoporosis, osteomalacia and other metabolic bone diseases.

Age
From **18 years** old to **64 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomize the study, simple randomization with individual unit is used, so that patients randomly select one of the cards containing the codes A or B so they enter one of the two treatment groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar Jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2020-02-01, 1398/11/12

Ethics committee reference number

IR.MUI.MED.REC.1398.574

Health conditions studied

1

Description of health condition studied

Rhinosinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Rhinosinusitis relapse

Timepoint

After the study

Method of measurement

Endoscopic symptoms of the nose or CT scan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group is considered as the intervention group and they are given vitamin D supplements. Patients are given vitamin D supplements according to the protocol and, based on the patients' access and preference they are given one vitamin D pearl (50,000 IU) once a week for 8 weeks or a 300,000 unit in 1 ml ampule every month (intramuscular injection)

Category

Treatment - Drugs

2

Description

Control group: The second group is considered as a control group and will not be subjected to any interference

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Hossein Ghazavi

Street address

Kashani Street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3233 0091

Email

h.ghazavi@gmail.com

2

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Hossein Ghazavi

Street address

Sofe blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3620 2020

Email

h.ghazavi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3668 0048

Email

sh_haghjoo@med.mui.ac.ir

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Ghazavi

Position

Assistant Professor of Otorhinolaryngology, Head and Neck Surgery

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Kashani Hospital

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3233 0091

Email

h.ghazavi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Ghazavi

Position

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City
Isfahan
Province
Isfahan
Postal code
7346181746
Phone
+98 31 3233 0091
Email
h.ghazavi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hossein Ghazavi
Position
Assistant Professor of Otorhinolaryngology, Head and Neck Surgery
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
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City
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Province
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Postal code
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Phone
+98 31 3233 0091
Email
h.ghazavi@gmail.com

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