Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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
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
Isfehan
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
Street address
Kashani Hospital
City
Isfahan
Province
Isfehan
Postal code
7346181746
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