Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study the effect of vitamin D on the treatment of patients with sinusonal polyposis

Protocol summary

Study aim
Determine the therapeutic effect of vitamin D in patients with sinusonal polyposis
Design
A clinical trial with a control group with parallel double-blind, randomized, and enveloped groups
Settings and conduct
This study was conducted on 60 patients in the ENT department of Imam Reza Hospital and Ghaem Hospital in Mashhad, Iran. The blinding is carried out and the patients , researcher alsoanalyzer were blinded and closed envelope has been used.
Participants/Inclusion and exclusion criteria
There is a lack of vitamin D and no chronic disease (which is likely to affect serum vitamin A levels or absorption and excretion), no smoking, no history of supplementing vitamin D in the last three months.
Intervention groups
Control group: A group receiving vitamin D1,000 units as 1 healthy min Capsule per day. Intervention group: A group that receives 5,000 units of vitamin D in 5 healthy min capsules per day.
Main outcome variables
Improvement of Sinonazal Polyposis Symptoms on the basis of Questionnaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180217038763N1**
Registration date: **2018-03-19, 1396/12/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-19, 1396/12/28**
Update count: **0**
Registration date
2018-03-19, 1396/12/28

Registrant information
Name
mehdi bakhshaee
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3841 3492
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-08-23, 1396/06/01
Expected recruitment end date
2018-05-22, 1397/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study the effect of vitamin D on the treatment of patients with sinusonal polyposis

Public title
Study the effect of vitamin D on nasal polyps
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Lack of serum vitamin D levels Patients satisfaction
Exclusion criteria:
Age
No age limit

Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Normal randomization method with Closed envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients give informed consent, but patients don't know whether they are in placebo group or the original drug group, also researcher don't know whether Patients are members of which group and the only aware person is analyzer.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
•Ethics committee of Mashhad University of Medical Sciences
Street address
Ghaem Hospital, Ahmad Abad AVE
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Approval date
2017-12-27, 1396/10/06
Ethics committee reference number
IR.MUMS.fm.REC.1396.535

Health conditions studied

1

Description of health condition studied
sinunasal polyposis
ICD-10 code
J33.8
ICD-10 code description
Other polyp of sinus

Primary outcomes

1

Description
Improvement of Sinonazal Polyposis Symptoms on the basis of Questionnaire
Timepoint
At the beginning of the study and 8 weeks after starting the use of vitamin D capsules
Method of measurement
Lund-kennedy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients in this group receive 1 x Healthy min capsule per day (vitamin D1000 unit of Minoo Pharmaceutical Company) for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in this group receive 5 x Healthy min capsule per day (vitamin D5000 unit of Minoo Pharmaceutical Company) for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
سعید حسینی
Street address
Ghaem Hospital, Ahmad Abad AVE
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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Ghoreishi building, Daneshgah AVE

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
سعید حسینی

Position
specialist

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

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Associate professor

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Person responsible for updating data

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Position
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Latest degree
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available