

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Study the effect of vitamin D on the treatment of patients with sinusoidal polyposis

#### Protocol summary

##### Study aim

Determine the therapeutic effect of vitamin D in patients with sinusoidal 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 also analyzer 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 D 1,000 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 bakhshae

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3841 3492

###### Email address

mehbakhsh@yahoo.com

##### 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 sinusoidal 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 Minoos 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 Minoos 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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saeed11848@yahoo.com

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Ghoreishi building, Daneshgah AVE

**City**

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**Email**

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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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mehdi Bakhshae

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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### Person responsible for updating data

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mehdi Bakhshae

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**Email**

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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