Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of oral Vitamin D Supplementation in recovery of the Patients with Chronic Rhinosinusitis with Nasal Polyps and Vitamin D insufficiency

Protocol summary

Study aim

Determining the efficacy of vitamin D in the recovery of patients with chronic rhinosinusitis with nasal polyps by age/sex/ Duration of treatment/disease grade/Intensity Endoscopic findings/underlying disease/Satisfaction Patient

Design

Clinical trial with control group with parallel and three-way blind and randomized groups on 72 patients. Random number table was used for randomization.

Settings and conduct

The present study will be performed on 72 patients with chronic rhinosinusitis and nasal polyps with moderate vitamin D deficiency refering to Matini Hospital in Kashan in the year of 1399.The patients will be randomly divided into treatment and placebo groups.Vitamin D will be given to the treatment group(50000 iu) per week orally for 8 weeks The other group will receive a placebo. After 8 weeks of supplementation, both groups will be examed again.The patient ,the physician and the analyser are unaware of the type of medication that each patient is taking.

Participants/Inclusion and exclusion criteria

Inclusion: -Definite chronic rhinosinusitis -Nasal polyps -Moderate vitamin D deficiency -Conscious consent Exclusion: -Taking systemic corticosteroids or other immonumodulatory drugs -Comorbidities and other chronic diseases -Pregnancy -Less than 10 years old of age

Intervention groups

The present study will be performed on 72 patients with chronic rhinosinusitis with nasal polyps and moderate vitamin D deficiency who will be referred to Matini Hospital in Kashan in 1399. These patients will be randomly divided into two groups: treatment and placebo. Vitamin D will be given to the group in oral doses(50000 iu) for 8 weeks and weekly. The other group will also receive a placebo. After 8 weeks of supplementation, the two groups will be reexamined.

Main outcome variables

Improvement of clinical symptoms and endoscopic findings in patients with chronic rhinosinusitis and nasal polyps

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200729048247N1**
Registration date: **2020-09-14, 1399/06/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-14, 1399/06/24**
Update count: **0**

Registration date

2020-09-14, 1399/06/24

Registrant information

Name

Leila Kalantari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5545 1421

Email address

kalantari-l@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-03, 1399/05/13

Expected recruitment end date

2020-10-04, 1399/07/13

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of oral Vitamin D Supplementation in recovery of the Patients with Chronic Rhinosinusitis with Nasal Polyps and Vitamin D insufficiency

Public title
Effect of Vitamin D in Rhinosinusitis with Nasal Polyps
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Chronic rhinosinusitis diagnosed Existence of nasal polyps on examination Vitamin D insufficiency documented in laboratory findings Conscious consent to study
Exclusion criteria:
Use of systemic corticosteroids or other immunosuppressive drugs pregnancy Age less than 10 years Existence of immunological, renal, digestive, glandular and musculoskeletal disorders such as rheumatoid arthritis, immunodeficiency, cystic fibrosis, ciliary dyskinesia, malabsorption
Age
From **10 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method was done by permuted blocked randomization first quadrople random block (a.b) was made. Then it was selected by using random number table of a.b letters(72) and based on the entrance number of patient to the study with the prepared random trail one of the a or b letter was excluded. Random sample was selected using <randomizer.ir> website.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In performing this intervention participants and outcome assessors and physician were all unaware of the type of medication the patient was taking. pills presented with exact similar size and color and packing and specific code that was allocated before with random number table.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of kashan University of Medical Sciences
Street address
Kashan University of Medical Sciences، ghotb ravandi blvd، kashan town
City
Kashan
Province
Isfehan
Postal code
5715985191
Approval date
2020-08-03, 1399/05/13
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.065

Health conditions studied

1

Description of health condition studied
Nasal polyps / Chronic rhinosinusitis
ICD-10 code
J33
ICD-10 code description
Nasal polyp / Chronic rhinosinusitis / vitamin D

Primary outcomes

1

Description
Improvement of disease grade
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Endoscopy before starting study and 8 weeks after starting treatment protocol

Secondary outcomes

1

Description
Serum level of vitamin D

Timepoint
Measurment of serum level of vitamin D at baseline and 8 weeks after the intervention
Method of measurement
Vitamin D blood test

2

Description
Headache Improvement
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

3

Description
Improvement of facial pain
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

4

Description
Improvement of hyposmia
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

5

Description
Decreasing of post nasal drip
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

6

Description
Decreasing of rhinorrhea
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

7

Description
Improvement of Nasal obstruction
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

8

Description
Improvement of congestion
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

9

Description
Improvement of fever
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

10

Description
Improvement of Halitosis
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

11

Description
Improvement of Drought
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

12

Description
Improvement of cough
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

13

Description
Improvement of ear pain
Timepoint
Before starting the intervention and 8 weeks later
Method of measurement
Visual analogue scale

Intervention groups

1

Description
Intervention group: treatment of vitamin D insufficiency with pearl 50000 u vitamin D per week until 8 weeks per oral(Produced by Zahravi Company)
Category
Treatment - Drugs

2

Description
Control group: placebo prescribed(With pearls of the same color, size and shape of vitamin D pearls) per week until 8 weeks per oral(Produced by Zahravi Company)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Matini Hospital
Full name of responsible person
Leila Kalantari
Street address
Kashan University of Medical Sciences، Ghotb Ravand Blvd، Kashan
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5545 1421
Email
leilakln284@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr Amirhossein Ahsani
Street address
Matini Hospital، Amir kabir st، Kashan Town
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5544 3022
Email
Leilakln284@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Leila Kalantari
Position
Medical doctor
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Kashan University of Medical Sciences, Qotb Ravandi Blvd,Kashan Town
City
Isfahan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5545 1421
Fax
Email
Kalantari-l@kaums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Leila Kalantari
Position
Medical doctor
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Kashan University of Medical Sciences, Qotb Ravandi Blvd,Kashan Town
City
Isfehan
Province
Isfehan
Postal code
8715973474
Phone

+98 31 5545 1421

Email

Leilakln284@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Leila Kalantari

Position

Med doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Kashan University of Medical Sciences, Qutb Ravand Boulevard,Kashan

City

Isfehan

Province

Isfehan

Postal code

8715973474

Phone

+98 31 5545 1421

Email

leilakln284@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

Any detail going to published

When the data will become available and for how long

starting 2 months after publication

To whom data/document is available

Any scientific and collegiate institutions

Under which criteria data/document could be used

Any analusis allowed

From where data/document is obtainable

leilakln284@gmail.com Leila kalantari

What processes are involved for a request to access data/document

About 1 month after request with email

Comments