

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of vitamin D efficacy in the patients with Allergic rhinitis in comparison with control group

Protocol summary

Study aim

Assessment of the effectiveness of vitamin D in treatment of patients with allergic rhinitis

Design

Clinical trial with control group, community-based and pragmatic with parallel groups, double blinded, and Phase 3 trials Randomized with table numbers, and design of 56 patients

Settings and conduct

This study was performed on 56 patients referred to the clinic of Ghaem Hospital in Mashhad. It was single-centered and double-blinded. Patients, researchers and analyst were blinded.

Participants/Inclusion and exclusion criteria

•Inclusion criteria: Patients with allergic rhinitis, which have been diagnosed by an immunologist with pric test. Having vitamin D deficiency Have consent to participate in the study •Exclusion criteria: Pregnancy Immunodeficiency diseases Sensitization to prescription drug

Intervention groups

In the intervention group, an allergic rhinitis routine treatment containing antihistamines will be taken with perl vitamin D for 8 weeks. In the control group, in addition to routine treatment containing antihistamines, they will receive placebo for 8 weeks.

Main outcome variables

Allergic rhinitis Symptoms on the basis of Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180217038763N2**

Registration date: **2019-02-06, 1397/11/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-06, 1397/11/17**

Update count: **0**

Registration date

2019-02-06, 1397/11/17

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

2018-05-22, 1397/03/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D efficacy in the patients with Allergic rhinitis in comparison with control group

Public title

The Efficacy of vitamin D in treating patients with nasal congestion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with allergic rhinitis Conscious Consent

Exclusion criteria:

Use of other drugs in addition to prescription drugs
Having vitamin D deficiency Pregnant and infected
people with immunodeficiency and skin diseases Having
allergies to prescription drugs

Age

From **6 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization method using random numbers
table using www.randomization.com

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and researchers will be unaware of the
intervention and control groups

Placebo

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

Ghoreishi building, Daneshgah AVE

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2018-12-12, 1397/09/21

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.459

Health conditions studied

1

Description of health condition studied

Allergic rhinitis

ICD-10 code

J30.9

ICD-10 code description

Allergic rhinitis, unspecified

Primary outcomes

1

Description

Clinical symptoms of Allergic rhinitis

Timepoint

At the beginning of the study, and weeks 4 and 8, after
starting taking vitamin D

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment of allergic rhinitis
include antihistamines with Perl D vitamin will be
received for 8 weeks

Category

Treatment - Other

2

Description

Control group: In the control group, in addition to routine
treatment, they will receive placebo for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mehdi Bakhshaei

Street address

Ahmad abad AVE, Ghaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3801 2753

Email

Mehbakhsh@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

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3841 3492

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

Fereshteh Esmati nia

Position

Non-faculty specialist

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Ghaem Hospital, Ahmad Abad AVE

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3841 3492

Email

f.esmatinia@yahoo.com

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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Postal code

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Phone

+98 51 3841 3492

Email

mehbakhsh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Associate professor

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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