

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Vitamin D supplementation over mild to moderate asthma outcome in 6-14 years old children

Protocol summary

Summary

Objectives: to determine the effect of vitamin D on the Frequency of asthma Exacerbation, the effect of vitamin D on S-IgE levels in serum of patients with asthma, the effect of vitamin D on FEV1 in patients with asthma, and the effect of vitamin D on the quality of life of patients with asthma. Design: This study is a clinical trial study that is randomized as Balanced Block randomizations. Setting and conduct: Asthmatic patients questionnaire included demographic information, clinical symptoms and laboratory tests is completed after obtaining the consent of the parents of the patients enrolled. They will be treated for 3 months according to the protocol, patients will be visited monthly. After 4 to 6 months of treatment, spirometry and positive laboratory tests will be repeated. Participants: children with mild to moderate asthma visited in asthma and allergy clinic afflicted to Children's Medical Center. Inclusion criteria's: 1- Patients with mild to moderate asthma diagnosed by physician 2 - Patients who are less than 3 months of treatment over the past 3 - patients between 6-14 years old; Exclusion criteria: 1 - Patients with severe asthma 2 - patient treated with immunotherapy or anti IgE 3 - Patients with chronic diseases like cardiovascular disease. Intervention: Vitamin D supplementation for 3 months + spray Fluticasone; control: spray Fluticasone as standard treatment of asthma. Main outcome measures: FEV1, FEV1/FVC, QOL, ACT

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110127784N1**
Registration date: **2012-12-01, 1391/09/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-01, 1391/09/11

Registrant information

Name

Behzad Darabi

Name of organization / entity

Tehran University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2237 9875

Email address

darabibh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Immunology, Asthma and Allergy Research Institute

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Vitamin D supplementation over mild to moderate asthma outcome in 6-14 years old children

Public title

The effect of Vitamin D supplementation over mild to moderate asthma outcome in 6-14 years old children

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:1- Patients with mild to moderate asthma diagnosed by physician2 - Patients who are less than 3 months of treatment over the past 3 - patients between 6-14 years old; Exclusion criteria: 1 - Patients with severe asthma 2 - patients treated with immunotherapy or anti IgE 3 - Patients with chronic diseases like cardiovascular disease

Age

From **6 years** old to **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Tehran university of medical sciences

Street address

6th floor,University Central Association,Keshavarz Blvd,Tehran

City

Tehran

Postal code**Approval date**

2012-03-17, 1390/12/27

Ethics committee reference number

130.2455.90.3

Health conditions studied**1****Description of health condition studied**

Asthma

ICD-10 code

J45

ICD-10 code description

Nonallergic asthma

2**Description of health condition studied**

Asthma

ICD-10 code

J45

ICD-10 code description

Mixed asthma

3**Description of health condition studied**

Asthma

ICD-10 code

J45

ICD-10 code description

Predominantly allergic asthma

Primary outcomes**1****Description**

FEV1

Timepoint

before and 4-6 months after intervention

Method of measurement

spirometry

2**Description**

FEV1/FVC

Timepoint

before and 4-6 months after intervention

Method of measurement

spirometry

3**Description**

Quality of life

Timepoint

before and 4-6 months after intervention

Method of measurement

Questionnaire

4**Description**

Asthma control

Timepoint

before and 4-6 months after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

S-IgE

Timepoint

before and 4-6 months after intervention

Method of measurement

RIDA

Intervention groups

1

Description

intervention: Vitamin D supplementation 500 U per day for 3 months + spray Fluticasone 100-500 microgram per day

Category

Treatment - Drugs

2

Description

control: spray Fluticasone 100-500 microgram per day as standard treatment of asthma

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

children medical center

Full name of responsible person

Behzad Darabi

Street address

NO.62 Gharib St, Keshavarz Blvd,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Immunology, Asthma and Allergy Research Institute

Full name of responsible person

Mostafa Moin MD

Street address

O.62 Gharib St, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Immunology, Asthma and Allergy Research Institute

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Allergy and clinical immunology unit, Central Medical Center

Full name of responsible person

Behzad Darabi MD

Position

Allergy and clinical immunology fellowship

Other areas of specialty/work

Street address

NO.62 Gharib St, Keshavarz Blvd

City

Tehran

Postal code

14194

Phone

009821:66920981-3

Fax

+98 21 6693 0024

Email

arabibh@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of medical sciences

Full name of responsible person

Mostafa Moin MD

Position

professor

Other areas of specialty/work

Street address

Asthma and Clinical Immunology unit, NO.62 Gharib St, Keshavarz Blvd

City

Tehran

Postal code

0098 21 66930024

Phone

+98 21669209813

Fax

+98 21 6642 8995

Email

iaari@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran university of medical sciences, Children
Medical Center, Allergy and clinical immunology unit

Full name of responsible person

Behzad Darabi

Position

Allergy and clinical immunology fellowship

Other areas of specialty/work**Street address**

Asthma and Clinical Immunology unit, NO.62 Gharib
St, Keshavarz Blvd

City

Tehran

Postal code

14194

Phone

+98 21669209813

Fax

+98 21 6693 0024

Email

darabibh@razi.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty