Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 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 - 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

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Behzad Darabi
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Tehran Univesity of medical siences
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Iran (Islamic Republic of)
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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.د

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
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NO.62 Gharib St, Keshavarz Blvd,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Immunology, Asthma and Allergy Research Institute
Full name of responsible person
Mostafa Moin MD
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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,Centeral Medical Center
Full name of responsible person
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Person responsible for updating data

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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