Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Vitamin D Supplementation on Improvement of Symptoms in Mild-to-Moderate Asthma Patients with Vitamin D Insufficiency and Deficiency

Protocol summary

Study aim

Evaluation of the effect of vitamin D supplementation on improvement of symptoms in mild-to-moderate asthma patients with vitamin D insufficiency and deficiency

Design

A randomized double-blinding clinical trial, with the parallel groups

Settings and conduct

This clinical trial is carried out in the pulmonary clinic of Al-Zahra Hospital in Isfahan and 132 patients with asthma and vitamin D deficiency/insufficiency will be randomly divided into four parallel groups. Then, two of these four groups will receive the placebo and the other two groups will receive vitamin D supplements.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with mild to moderate asthma and vitamin D deficiency/insufficiency. Exclusion criteria include diagnosis of COPD, sarcoidosis, hyperthyroidism, kidney stones, active tuberculosis, vitamin intolerance, liver failure, renal failure, lymphoma, or other malignant tumors have not improved in more than two years. , or treatment with anticonvulsants, vitamin D supplements, treatment with systemic corticosteroids for more than 3 months before the study, breastfeeding or pregnancy, serum calcium above 2.65 mmol/L, exacerbation of asthma in the three months, and active/inactive smoking.

Intervention groups

Patients with asthma with vitamin D insufficiency/deficiency receive commonly used asthma control medications (inhaled sprays), which will be the same in both groups. For patients with vitamin D deficiency, in the case group, 50,000 u of vitamin D supplements will be given orally every week for up to 6 weeks and then 1000 U every 4 weeks. Patients with inadequate vitamin D levels will also be prescribed 1000 U every 4 weeks. In the control group with a deficiency/insufficient level of vitamin D, the placebo will be prescribed.

Main outcome variables

Severity of asthma symptoms; FEV1 parameters; FVC; Vitamin D level (25 OHD)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N10**
Registration date: **2020-10-24, 1399/08/03**
Registration timing: **retrospective**

Last update: **2020-10-24, 1399/08/03**
Update count: **0**

Registration date

2020-10-24, 1399/08/03

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date
2015-03-21, 1394/01/01
Actual recruitment end date
2016-03-20, 1395/01/01
Trial completion date
2016-03-20, 1395/01/01

Scientific title
The Effect of Vitamin D Supplementation on Improvement of Symptoms in Mild-to-Moderate Asthma Patients with Vitamin D Insufficiency and Deficiency

Public title
The Effect of Vitamin D Supplementation on Improvement of Symptoms in Asthma Patients with Vitamin D Insufficiency and Deficiency
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mild-to-moderate asthma Patients with vitamin D insufficiency and deficiency Being consent to participate in the study
Exclusion criteria:
Diagnosis of chronic obstructive pulmonary disease (COPD) Sarcoidosis Hyperthyroidism Kidney stones Active tuberculosis Vitamin D intolerance Liver failure Kidney failure Suffering from lymphomas or other malignant tumors that have not healed in more than two years of treatment Treatment with anticonvulsant drugs, vitamin D supplements Treatment with systemic corticosteroids for more than 3 months prior to study Breastfeeding or pregnancy a basal serum calcium concentration of >2.65 mmol / L Exacerbation of asthma in the three months before the study Active or inactive smoking
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **132**
Actual sample size reached: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
66 patients with asthma and vitamin D deficiency and also 66 patients with asthma and insufficient levels of vitamin D will be selected using simple randomization. These two groups of 66 people are then coded with the aid of random allocation software and are automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly studied in one of the two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
To blind the study, vitamin D and placebo will be prepared in the same shape and color by the pharmacist before the intervention. These drugs will then be coded and made available to the researcher. They also prescribe them without knowing the type of any of the drugs. Also, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2016-10-10, 1395/07/19
Ethics committee reference number
IR.MUI.REC.1395.3.544

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45
ICD-10 code description
Asthma

Primary outcomes

1

Description
Control of asthma symptoms
Timepoint
Before the intervention and three months after the

intervention

Method of measurement

Asthma Control Test (ACT score)

2

Description

FEV1 parameter

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Spirometer device

3

Description

FVCparameter

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Spirometer device

4

Description

Serum vitamin D level

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Radioimmunoassay method

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients with asthma and vitamin D deficiency, in addition to receiving conventional asthma control medications (SymbiCort inhalation spray), received placebo for 6 weeks.

Category

Placebo

2

Description

Control group: Patients with asthma and insufficient levels of vitamin D, in addition to receiving commonly used asthma control drugs (SymbiCort inhalation spray), received placebo for 6 weeks.

Category

Placebo

3

Description

Intervention group: Patients with asthma and vitamin D deficiency, in addition to taking the usual asthma control medications (SymbiCort inhalation spray), take a 50,000-unit vitamin supplement orally every week for up to 6 weeks until the serum level of vitamin D reaches more than 20 ng/ml, then they will be prescribed 1000 units daily.

Category

Treatment - Drugs

4

Description

Intervention group: Patients with asthma and inadequate vitamin D level, in addition to taking the usual asthma control medications (SymbiCort inhalation spray), will be prescribed 1000 unit vitamin supplement orally daily for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Mohammad Emami Ardestani

Street address

Lung Clinic, Al-Zahra Hospital, Hezar Jerib Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Emami Ardestani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Emami Ardestani

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Azam Movahedi

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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