Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Supplements Containing Vitamin D and Selenium to Asthma Treatment on Symptoms and Immunological Alterations in Patients with Moderate to Severe Asthma

Protocol summary

Study aim
The effect of vitamin D, folic Acid, selenium, zinc, and copper supplements was investigated in patients with moderate to severe asthma.

Design
In this phase 2 parallel non-probability purposive sampling method study, 65 patients were divided not randomly in two groups. The first group was treated by 1200 IU of vitamin D3 daily and the second group was treated by 10 ml of Asmavit syrup daily for two months.

Settings and conduct
In this study 65 patients were divided into two groups by non-probability purposive sampling method: The first group was treated by 1200 IU of vitamin D3 daily and the second group was treated by 10 ml of Asmavit syrup (Vitabiotics Company, England) daily for two months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Patients with moderate to severe asthma according to the criteria adopted to determine the severity of the disease. 2- Age above 6 years. 3- patients satisfaction Exclusion criteria: 1- Pregnancy 2- Unstable asthma

Intervention groups
The first group was treated by 1200 IU of vitamin D3 daily and the second group was treated by 10 ml of Asmavit syrup daily for two months.

Main outcome variables
Clinical symptoms and Immunological Alterations

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150716023235N16**
Registration date: **2020-09-04, 1399/06/14**
Registration timing: **registered_while_recruiting**
Last update: **2020-09-04, 1399/06/14**
Update count: **0**

Registration date
2020-09-04, 1399/06/14

Registrant information

Name
Farahzad Jabbari Azad

Name of organization / entity
Allergy Research Center, Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Supplements Containing Vitamin D and Selenium to Asthma Treatment on Symptoms and Immunological Alterations in Patients with Moderate to Severe Asthma

Public title

The Effect of Vitamin D and Selenium Supplements

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with moderate to severe asthma according to the criteria adopted to determine the severity of the disease. Age above 6 years patients satisfaction

Exclusion criteria:

Pregnancy Unstable asthma

Age

From **6 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Not 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

Mashhad University of Medical Sciences

Street address

Ghoreishi building Ethics Committee of Mashahd University of Medical Science

City

Mashhad

Province

Razavi Khorasan

Postal code

9175711111

Approval date

2014-10-25, 1393/08/03

Ethics committee reference number

IR.MUMS.REC.1393.178

Health conditions studied

1

Description of health condition studied

Patients with Moderate to Severe Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Clinical symptoms

Timepoint

before and after intervention

Method of measurement

ACT and ACQ questionnaire

2

Description

Immunological Alterations

Timepoint

before and after intervention

Method of measurement

Elisa

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group was treated by 1200 IU of vitamin D3 daily for two months.

Category

Treatment - Drugs

2

Description

Intervention group: the second group was treated by 10 ml of Asmavit syrup (Vitabiotics Company, England) daily for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy clinic of Ghaem Hospital

Full name of responsible person

Mansoor Ahoon

Street address

Ahmad abad AVE, Ghaem hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Ahmad Abad Boulevard, Ghaem Hospital
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tafaghodim@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
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Position
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available