

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 51 1801 2770

###### Email address

jabbarif@mums.ac.ir

##### 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 Mashhad 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91766-9919

**Phone**

+98 51 3801 2780

**Email**

dr.m.ahoon@gmail.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**

Ahmad Abad Boulevard, Ghaem Hospital

**City**

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**Province**

Razavi Khorasan

**Postal code**

91766-9919

**Phone**

+98 51 3841 2081

**Email**

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

**Full name of responsible person**

Mansoor Ahoon

**Position**

Subspeciality

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Immunology

**Street address**

No. 7, Bokharaei 11 St., Ahmad Abad ave., Mashhad

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dr.m.ahoon@gmail.com

## Person responsible for scientific inquiries

**Contact**

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Mashhad University of Medical Sciences

**Full name of responsible person**

Mansoor Ahoon

**Position**

Subspeciality

**Latest degree**

Medical doctor

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## Person responsible for updating data

**Contact**

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Mashhad University of Medical Sciences

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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