# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Nov 2026

## The effect of vitamin D on pulmonary function and serum level of interleukin 10 and antioxidant activity in patient with moderate to severe asthma.

## Protocol summary

**Study aim**
Determining the effect of vitamin D administration on lung function and serum level of interleukin 10 and total serum antioxidant activity in patients with moderate to severe asthma with vitamin D deficiency

**Design**
Clinical trial with control group, with parallel group; Double-blind, randomized

**Settings and conduct**
This study is performed in Valiasr Hospital in Birjand, South Khorasan Province. Sixty patients are randomly divided into intervention and control groups. At the beginning of the study and before starting treatment, antioxidant activity and interleukin 10 were evaluated from serum levels. Then the intervention was performed for 3 months. Blood samples were taken from patients and antioxidant and interleukin 10 parameters were measured. In this study, the executive steps were performed by the administrator and the patients and the evaluating nurse did not know the patient group.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: including people with moderate to severe asthma without association with systemic, heart, liver, infectious, diabetes and kidney diseases referred to Vali-e-Asr Hospital for outpatient treatment and exclusion criteria: Reluctance to cooperate in the continuation of the project, presence of disease including diabetes mellitus, CAD, CKD, PTE and bacterial pneumonia, death, non-medication, changes in treatment, addition of other disease as well as patients taking antioxidant supplement or medication and any medication that affects the mitochondrial system and antioxidant storage.

**Intervention groups**
The intervention group consisted of 30 patients with asthma who received 1 pearl 2,000 units of vitamin D daily for 3 months. The control group consisted of 30 patients with asthma who received 1 pearl containing glucose 1 daily for 3 months.

**Main outcome variables**
Total Antioxidant Capacity Interleukin 10

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190721044288N1**
Registration date: **2020-10-27, 1399/08/06**
Registration timing: **retrospective**

Last update: **2020-10-27, 1399/08/06**
Update count: **0**

**Registration date**
2020-10-27, 1399/08/06

**Registrant information**

**Name**
Ali Mirshahi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3871 5553

**Email address**
dr.ali.mirshahi@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-04-19, 1398/01/30

**Expected recruitment end date**
2019-10-22, 1398/07/30

**Actual recruitment start date**

2019-04-19, 1398/01/30

**Actual recruitment end date**

2020-01-20, 1398/10/30

**Trial completion date**

2020-02-19, 1398/11/30

**Scientific title**

The effect of vitamin D on pulmonary function and serum level of interleukin 10 and antioxidant activity in patient with moderate to severe asthma.

**Public title**

Effect of vitramin D in asthma

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

moderate to severe asthma treated with inhaled corticosteroid (ICS) vitamin D deficiency No systemic disease No diabetes No infectious disease No liver disease No heart disease No kidney disease

**Exclusion criteria:**

patient expired patient who do not use his drug add new systemic disease change of treatment Patients taking antioxidant drugs Use of any medication that affects the mitochondrial system and antioxidant storage

**Age**

From **16 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple random lottery method

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Study participants were not aware of the drug used. The control group also received placebo of the same shape, color and size as the intervention group drug. The outcome assessor (co-nurse) assessed the outcome without informing the patient group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Birjand University of Medical Sciences

**Street address**

Ghaffari Str

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717811674

**Approval date**

2018-10-29, 1397/08/07

**Ethics committee reference number**

ir.bums.REC.1397.185

## Health conditions studied

### 1

**Description of health condition studied**

Asthma

**ICD-10 code**

J45

**ICD-10 code description**

Asthma

## Primary outcomes

### 1

**Description**

Serum levels of antioxidants in the blood serum of patients

**Timepoint**

Measurement of serum antioxidant levels at the beginning of the study and 3 months after starting vitamin D intake

**Method of measurement**

Use of thiobarbituric acid method

### 2

**Description**

Serum levels of interleukin 10 in the blood serum of patients

**Timepoint**

Measurement of serum interleukin level 10 at the beginning of the study and 3 months after starting vitamin D intake

**Method of measurement**

Using the commercial kit by ELISA method

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Control group: received 1 pearl containing glucose daily (made by Birjand School of Pharmacy) as a placebo for 3 months.
**Category**
Placebo

### 2

**Description**
Intervention group: received 1 unit of pearl vitamin D 2000 units (manufactured by Dana Pharmaceutical Company) daily for 3 months.
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Valiasr Hospital, Birjand
**Full name of responsible person**
Dr. Ali Mirshahi
**Street address**
Moallem Str
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717811674
**Phone**
+98 56 3232 3232
**Email**
oabstudent@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Dr. Tooba Kazemi
**Street address**
Ghaffari Str
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717811674
**Phone**
+98 56 3238 1200
**Email**
oabstudent@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Birjand University of Medical Sciences
**Proportion provided by this source**
50
**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**
Birjand University of Medical Sciences
**Full name of responsible person**
Zabihullah Mohaghegh
**Position**
Student
**Latest degree**
Bachelor
**Other areas of specialty/work**
General Practitioner
**Street address**
Moallem Str
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717811674
**Phone**
+98 56 3232 3232
**Email**
oabstudent@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Dr. Gholamreza Mortazavimoghaddam
**Position**
Faculty of member
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Internal Medicine
**Street address**
Ghaffari Str

**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717811674
**Phone**
+98 56 3232 3232
**Email**
oabstudent@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Dr. Ali Mirshahi
**Position**
Resident of Internal Studies
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Internal Medicine
**Street address**
Moallem Str
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717811674
**Phone**
+98 56 3232 3232
**Email**
oabstudent@gmail.com

## 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 are no plans to publish it
**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