

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 vitamin 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

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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

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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

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

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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

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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
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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 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