

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Effect of oral vitamin D supplementation on serum markers of oxidative stress and antioxidant in asthmatic children and its comparison with control group.

Protocol summary

Summary

Despite numerous publications on the relationship between vitamin D and immune system, yet the precise role of vitamin D in asthma from clinical viewpoint is contraversive .The purpose of randomized, double-blind placebo-controlled study, was to determine the levels of oxidative stress and antioxidant markers levels in asthmatic children after oral vitamin D prescription and its comparison with the control group. Design and implementation: In this study, 60 children with asthma hospitalization randomly divided into two groups of 30 subjects. Interventions: One group received a single oral dose of 100,000 IU of vitamin D and the second group that its randomly selected, received sweet almond oil as placebo. Inclusion criteria: asthma,Ardabil Bouali Hospital admission. Exclusion criteria: pneumonia, Rickets, the use of high-dose vitamin D in the last three months, severe malnutrition and diseases such as cystic fibrosis and metabolic syndrome. the serum level of 25 (OH) vitamin D will be measured prior to intervention and at the end of study (10 days). serum glutathion and total antioxidant capacity will be measured at the end of study (after 10 days of treatment). The effect of Vitamin D supplementation on clinical signs and symptoms of asthma will be evaluated as primary outcome measure. the serum level of oxidative stress and antioxidant makers will be evaluated as second primary outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014053117843N3**

Registration date: **2014-08-04, 1393/05/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-04, 1393/05/13

Registrant information

Name

Adel Ahadi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 45 1773 1210

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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral vitamin D supplementation on serum markers of oxidative stress and antioxidant in asthmatic children and its comparison with control group.

Public title

Vitamin D supplementation and its effect on markers of

oxidative stress and antioxidant in asthmatic children.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: asthma; Bouali Hospital admission.

Exclusion criteria: pneumonia; Rickets; the use of high-dose vitamin D in the last three months; severe malnutrition; diseases such as cystic fibrosis.

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical Sciences.

Street address

Ardabil, University Ave, Ardabil University of Medical Sciences.

City

Ardabil.

Postal code

Approval date

2013-09-15, 1392/06/24

Ethics committee reference number

9220

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Clinical improvement

Timepoint

8 weeks

Method of measurement

Spirometry

Secondary outcomes

1

Description

Glutathione

Timepoint

8 weeks

Method of measurement

Folin-Ciocalteu reagent

2

Description

serum Total antioxidant capacity (TOC)

Timepoint

10 days

Method of measurement

Spectrophotometry

Intervention groups

1

Description

In this study to intervention group, prescribed vitamin D vial 100000 IU, orally, once.

Category

Treatment - Drugs

2

Description

In this study to placebo group, prescribed Sweet oil vial, orally, once.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali Hospital

Full name of responsible person

Dr adel ahadi

Street address

Ardabil, Varzesh square, Bouali Hospital.
City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Hadi Piri dogahe

Street address

Ardabil, Daneshgah Street, Ardabil University of Medical Sciences.

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences.

Full name of responsible person

Dr Adel Ahadi

Position

Ardabil, Boali Hospital.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Boali Hospital

Full name of responsible person

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Position

Pharmacology Phd

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

dr Leila Katebi

Position

pediatric assistant

Other areas of specialty/work

Street address

City

Ardabil

Postal code

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty