

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the vitamin D supplementation effect on the course of asthma

Protocol summary

Study aim

effect of vitamin D supplementation on asthma course

Design

single arm study without randomization and blinding

Settings and conduct

Besat Hospital Patients Considering inclusion and exclusion Criteria who were willing to participate in the project. After obtaining consent from the patient and the parents, they examined for serum vitamin levels D by blood sampling. Samples are collected and then extracted from the plasma by a vitamin D assay kit under the supervision of a laboratory expert or pathologist. People with vitamin D deficiency are enrolled in the study. After the completion of the treatment period, the patient is re-tested and paraclinical evaluated for severity of asthma. According to the Approved guideline by the Northamptonshire Prescribing Advisory Group, the treatment of vitamin D deficiency: patients with deficiency of vitamin D (<25nmol/l): At the primary care level the Fultium-D3 800IU capsule, 4 capsules daily for 84 days (12 weeks) At the second care level, D3-50 50,000 IU, one tablet daily for 6 days or Cholecalciferol 300,000 units can be injected intramuscular monthly for 3 months For patients with insufficiency of vitamin D (25-50 nmol/l), according to the patient's calcium level and according to the physician opinion.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patients with asthma exclusion criteria: 1-Unwilling to participate in the study 2. Identify any disorder or chronic illness (including kidney and liver disease) 3. Malignancy 4. Muscular musculoskeletal disorders including rickets and osteomalacia 5. Vitamin D intake as a medicine and nutritional supplement 6.Use of drugs that may have an effect on vitamin D metabolism, including anticonvulsants 7. Normal level of vitamin D after measurement

Intervention groups

Patients aged 6 to 18 years with asthma

Main outcome variables

FEV1 exacerbation The severity of asthma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171222037986N1**

Registration date: **2018-08-01, 1397/05/10**

Registration timing: **retrospective**

Last update: **2018-08-01, 1397/05/10**

Update count: **0**

Registration date

2018-08-01, 1397/05/10

Registrant information

Name

Rasol Nasiri Kalmarzi

Name of organization / entity

Kurdistan university of medical scions

Country

Iran (Islamic Republic of)

Phone

+98 87 3323 0524

Email address

rnasiri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-13, 1396/12/22

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

2015-04-01, 1394/01/12

Actual recruitment end date

2017-04-20, 1396/01/31

Trial completion date

empty

Scientific title

Evaluation of the vitamin D supplementation effect on the course of asthma

Public title

The role of vitamin D in the course of asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with asthma based on history and physical examination or PFT findings. Willing to participate in the study No previous disease are known. Vitamin D Deficiency

Exclusion criteria:

The person's unwillingness to continue to collaborate on the study Recognition of any disorder or chronic illness during the study (including kidney or liver disease) Malignancy Musculoskeletal disorders including rickets and osteomalacia Taking vitamin D 'as a medicine or a nutritional supplement Use of drugs that may have an effect on vitamin D metabolism, including anticonvulsants The normal level of vitamin D after measuring its serum levels

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Actual sample size reached: **52**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Science

Street address

Kurdistan University of Medical Sciences Vice Chancellor in Research Affair, Pasdaran Ave., Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

1344666177.

Approval date

2018-03-13, 1396/12/22

Ethics committee reference number

IR.MUK.REC.1396/366

Health conditions studied

1

Description of health condition studied

asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Asthma severity

Timepoint

12 weeks

Method of measurement

based on examinations, PFT and History tacking

2

Description

exacerbation

Timepoint

Upon arrival to 12 weeks later

Method of measurement

Coughing attacks, shortness of breath and wheezing caused by exacerbation of asthma

3

Description

FEV1

Timepoint

Coming in and 12 weeks later

Method of measurement

Spirograph chart

Secondary outcomes

empty

Intervention groups

1

Description

According to the Approved guideline by the Northamptonshire Prescribing Advisory Group, the treatment of vitamin D deficiency: patients with deficiency of vitamin D (<25nmol/l): At the primary care level the Fultium-D3 800IU capsule, 4 capsules daily for 84 days (12 weeks) At the second care level, D3-50 50,000 IU, one tablet daily for 6 days or Cholecalciferol 300,000 units can be injected intramuscular monthly for 3 months For patients with insufficiency of vitamin D (25-50 nmol/l), according to the patient's calcium level and according to the physician opinion. the clinic of Besat Hospital of Sanandaj

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Rasoul Nasiri Kalmarzi

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Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

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6618634683

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Email

rasool_nsr@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Rasoul Nasiri Kalmarzi

Street address

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Saywan Ahmadi

Position

Medical Student, Member of the Student Research Committee

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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saywanahmadi1992@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Rasoul Nasiri Kalmarzi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is from the proposal, raw data and project reports

When the data will become available and for how long

Data is available from the legal system six months after publication for two years

To whom data/document is available

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

By submitting a request to the Delegation for Research and Technology and approving the Ethics Committee - Rasoul Nasiri Kalmarzi MD

What processes are involved for a request to access data/document

After submitting a request to the Kurdistan Research and Technology Dept. of Science and Technology, a call for submission is given.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Behzad Khalafi

Position

Research Assistant (Researcher Deputy Soldier)

Latest degree

Medical doctor

Other areas of specialty/work

Public Health

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