

# 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

#### Street address

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

#### City

Sanandaj

#### Province

Kurdistan

#### Postal code

6618634683

#### Phone

+98 87 3323 0524

#### 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

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

#### City

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Kurdistan

#### Postal code

6618634683

#### Phone

+98 87 3366 4645

#### Email

rasool\_nsr@yahoo.com

#### 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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#### Email

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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rasool\_nsr@yahoo.com

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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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