Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Sanandaj

Province
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

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

City
Sanandaj

Province
Kurdistan

Postal code
6618634683

Phone
+98 87 3366 4645

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
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

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 Deuty Soldier)
Latest degree
Medical doctor
Other areas of specialty/work
Public Health
Street address
Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran
City
Sanandaj
Province
Kurdistan
Postal code
6618634683
Phone
+98 87 3366 4645
Email
khalafi.behzad70@gmail.com

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