

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of Vitamin D Injection Dose Adjustment on Vitamin D Deficient Asthmatic Patients Improvement and Treatment

Protocol summary

Study aim

Studying of Vitamin D Injection Effectiveness on Asthmatic Patients Improvement and Treatment

Design

A prospective open pilot study with 20 asthmatic patients in a non-blind and Single group, also non-randomised and Based on a before and after study design

Settings and conduct

Moderate to severe asthmatic patients in Bu Ali Hospital who are diagnosed by spirometry test and St. George's respiratory questionnaire (SGRQ), considering inclusion and exclusion criteria, take blood test. Vitamin D deficient patients rolls in the study and recieve two vitamin D 300,000 IU IM injection with a one month gap between. two months after the start of the study, patients take spirometry test and Fill in SGRQ and Take another blood test to evaluate 25(OH)D3 baseline again. At the end, the results will be compared with those results collected in the start of the study to observe the improvement procedure.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Moderate to Severe Asthma, ages between 18 to 75 also They must be under treatment, Plus Vitamin D deficient. Exclusion criteria: Patients with infectious lung disease, pregnant and breastfeeding women, patients with parathyroid problems and Patients with severe kidney and liver disease

Intervention groups

Intervention group: According to their blood test result, These patients are Vitamin D deficient and Should receive two Vitamin D ampoule 300,000 international units(IU) Intramuscularly(IM) with a one month gap between. Control group: There is no control group in this study; hence, at the end the results will be compared with those results collected in the start of the study to observe the improvement procedure.

Main outcome variables

25(OH)D3 Baseline: Forced Expiratory Volume In First Second: Forced Vital Capacity: Proportion of a Person's Vital Capacity that He Is Able to Expire in The First Second of Forced Expiration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160813029327N14**

Registration date: **2018-07-17, 1397/04/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-17, 1397/04/26**

Update count: **0**

Registration date

2018-07-17, 1397/04/26

Registrant information

Name

Ramin Abrishami

Name of organization / entity

Islamic Azad University, Pharamceutical sciences branch

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-17, 1396/07/25

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Vitamin D Injection Dose Adjustment on Vitamin D Deficient Asthmatic Patients Improvement and Treatment

Public title

Assessment of Vitamin D Effectiveness on Asthma Treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Moderate to Severe Asthma Under Treatment Asthmatic Patients Vitamin D Deficient Patients

Exclusion criteria:

Patients with Infectious Lung Disease Pregnant and Breastfeeding Women Patients with Parathyroid Problems Severe Kidney Disease Severe Liver Disease

AgeFrom **18 years** old to **75 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **20****Randomization (investigator's opinion)**

Not randomized

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**

Ethics Committee of Tehran Islamic Azad University of Pharmaceutical Sciences

Street address

No 99, Yakhchal Street, Gholhak Area, Shariati Ave

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Tehran

Province

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Postal code

6466_19395

Approval date

2017-02-01, 1395/11/13

Ethics committee reference number

IR.IAU.PS.REC.1395.70

Health conditions studied**1****Description of health condition studied**

Asthma

ICD-10 code

J45

ICD-10 code description

Disorder of The Airways

Primary outcomes**1****Description**

25(OH)D3 Baseline

Timepoint

Assessment of 25(OH)D3 Baseline before Starting The Intervention and Again 2 Months After The First Injection of Vitamin D Ampoule

Method of measurement

Blood Test

2**Description**

Forced Expiratory Volume In First Second

Timepoint

Assessment of Forced Expiratory Volume In First Second, before Starting The Intervention and Again 2 Months After The First Injection of Vitamin D Ampoule

Method of measurement

Spirometry Device

3**Description**

Forced Vital Capacity

Timepoint

Assessment of Forced Vital Capacity, before Starting The Intervention and Again 2 Months After The First Injection of Vitamin D Ampoule

Method of measurement

Spirometry Device

4**Description**

Proportion of a Person's Vital Capacity that He Is Able to Expire in The First Second of Forced Expiration

Timepoint

Assessment of Proportion of a Person's Vital Capacity that He Is Able to Expire in The First Second of Forced Expiration, before Starting The Intervention and Again 2 Months After The First Injection of Vitamin D Ampoule

Method of measurement

Spirometry Device

Secondary outcomes

1

Description

Quality of Life

Timepoint

Assessment of Quality of Life of The Patient before Starting The Intervention and Again 2 Months After The First Injection of Vitamin D Ampoule

Method of measurement

St. George's Respiratory Questionnaire

Intervention groups

1

Description

Intervention group: It includes asthmatic patients with 25(OH)D3 baseline under 20 ng/ml (Vitamin D deficiency). So They need to take blood test in order to evaluate 25(OH)D3 baseline first. After they are diagnosed with Vitamin D deficiency, Vitamin D Ampoule 300,000 IU is injected to them intramuscularly(IM) once in the first month of the study and the second Vitamin D Ampoule injection, one month after the first injection, is taken again IM. Furthermore, their respiratory condition should be checked by the spirometry test and St. George's respiratory questionnaire once in the first step of the study and Then again, two months later. Moreover, another blood test two month after the first injection should be taken to see if their 25(OH)D3 baseline is corrected. Finally the results of Blood test, Spirometry test and St. George's respiratory questionnaire which were collected in the first step of the study will be compared with the ones collected after two months of follow up to see if this type of intervention is beneficial for the patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Hamid Reza Moezi

Street address

Damavand Avenue, Imam Hossein Square, Tehran

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17117

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hmoezzi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arian Dokht Eini Sadr

Street address

No. 99, Islamic Azad University of Pharmaceutical Science, Yakhchal St, Gholhak Area, Shariati Ave

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Email

arianeinisadr@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Arian Dokht Eini Sadr

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Mehdi Rajabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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

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Student

Latest degree

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

Undecided - It is not yet known if there will be a plan to make this available

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