

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of vitamin D supplementation on airways function and inflammation in 10-50 years old asthmatics in rasool e akram hospital

Protocol summary

Summary

Improving asthma treatment is the goal of this study. This is a randomized clinical trial in which 120 asthmatic 10-50 years old patients are divided randomly in 2 groups after confirming their asthma with spirometry and GINA protocol and ruling out any other chronic lung diseases in them. At the beginning their lung functions will be evaluated with spirometry and oscillometry and 3cc blood will be sampled for tests. Then they will be prescribed their standard asthma treatment but the case group will have vitamin D supplementation; 100000 units of vitamin D intramuscular and 50000 units of Vit D oral weekly for 6 months plus their routine asthma treatment. If they have not had any asthma attack or used systemic corticosteroid they will be evaluated after 8 weeks and at the end of study again. The exams will be repeated.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201302079608N1**

Registration date: **2013-09-10, 1392/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-10, 1392/06/19

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D supplementation on airways function and inflammation in 10-50 years old asthmatics in rasool e akram hospital

Public title

Vitamin D effects in asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 10-50; Asthma diagnosis according to spirometry and GINA guidelines; Ruled out of COPD and any chronic lung diseases; No asthma attack in previous 3 months; No pregnancy; No malignancy; sarcoidosis; renal or intestinal diseases or hyper sensitivity to vitamin D; No use of systemic corticosteroid or anti convulsant
Exclusion criteria No inclusion criteria; No consent to this program

Age

From **10 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

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Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Corner of Ghods street, Keshavarz boulevard

City

Tehran

Postal code

-

Approval date

2012-10-12, 1391/07/21

Ethics committee reference number

19827

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Airway function

Timepoint

Before and after 8week, 16 week and after 6month

Method of measurement

Oscilometry

2

Description

Airway function

Timepoint

Before and after 8week, 16 week and after 6month

Method of measurement

Spirometry

3

Description

serum vitamin D level

Timepoint

Before and after 8week, 16 week and after 6month

Method of measurement

eliza (serum)

Secondary outcomes

1

Description

Serum Ig E level

Timepoint

before and after study

Method of measurement

ELIZA

Intervention groups

1

Description

Patient in the case group will receive appropriate Asthma controller according their Asthma stage which is inhaled oral corticosteroid with appropriate dose and extra than standard asthma treatment they will use vitamin D supplementation .they will inject 100000unit of Vit D intramuscular followed by 50000 unit Vit D orally weekly for 6 months.

Category

Treatment - Drugs

2

Description

Patients in the control group only receive asthma controller drug as oral inhaler corticosteroid according their asthma stage with appropriate dose without any supplementation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool e Akram Hospital

Full name of responsible person

Dr Morteza Fallahpour

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Niayesh street, Sattar Khan street

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Web page address

-

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Research Division of Tehran University of Medical Sciences

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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

Tehran 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**

Tehran University of Medical Sciences

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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