

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

Saba Arshi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 66566101

##### Email address

s-arshi@sina.tums.ac.ir

##### 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

Serume 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

**Street address**

Niayesh street, Sattar Khan street

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fallahpour.morteza@gmail.com

**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

**Street address**

Corner of Ghods Street, Keshavarz boulevard

**City**

Tehran

**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

**Full name of responsible person**

Morteza Fallahpour

**Position**

Fellow of Allergy and Clinical Immunology

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Unit3, Number27, Siami Avenue, SattarKhan Street

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

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**Full name of responsible person**

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Assisted Professor

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

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**Full name of responsible person**

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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*