

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluating the effect of vitamin D replacement on the distance during six minute walk test in patients with COPD

#### Protocol summary

##### Summary

The aim of this study is to compare the distance during 6 minute walk test before and after vitamin D replacement. Stable COPD outpatients with vitamin D deficiency or insufficiency will enter the study. Those with renal failure, kidney stone, hyper parathyroidism, advanced musculo-skeletal and degenerative joint disorders with inability to walk, peripheral vascular disease, Pulmonary artery pressure more than 50mmHg, left ventricular ejection fraction of less than 40%, and admission for COPD exacerbation within previous 2 weeks will be excluded. Twenty five COPD outpatients will be studied. The distance during 6 minute walk test will be measured at presentation. They will receive Vitamin D pearls 50,000 IU weekly for 6 weeks. After 3 months, the second 6 minute walk test will be done and the maximum distance and during the test will be compared with those of the first test. Pulmonary function test are also measured before and three month after the intervention. To be assured from intestinal absorption of oral vitamin D, serum 25 hydroxy vitamin D and 24 hour urinary calcium excretion will be measured after 2 months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013021012419N1**  
Registration date: **2013-04-20, 1392/01/31**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-04-20, 1392/01/31

##### Registrant information

##### Name

Mehrnaz Asadi Gharabaghi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61192646

##### Email address

asadi\_m@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2013-01-20, 1391/11/01

##### Expected recruitment end date

2013-06-20, 1392/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of vitamin D replacement on the distance during six minute walk test in patients with COPD

##### Public title

The effect of vitamin D replacement on overall physical performance of patients with chronic lung disease

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Outpatients with COPD and Vitamin D deficiency or insufficiency  
Exclusion criteria: Chronic renal failure, Urolithiasis, Parathyroid disease, Peripheral vascular disease, Inability to walk because of

neuromuscular or advanced degenerative joint disease;Pulmonary artery pressure more than 50 mmHg,Left ventricular ejection fraction less than 40% ,admission for COPD exacerbation within previous 2 weeks

#### **Age**

From **40 years** old to **84 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **25**

#### **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**

Tehran University of Medical Sciences

###### **Street address**

Central official building,Ghods Street,Keshavarz Boulevard

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2012-10-22, 1391/08/01

##### **Ethics committee reference number**

91/210/17957/3

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Chronic Obstructive Pulmonary Disease

##### **ICD-10 code**

J44.9

##### **ICD-10 code description**

chronic: bronchitis: asthmatic (obstructive)  
emphysematous with: airways obstruction emphysema  
obstructive: asthma bronchitis tracheob

### **Primary outcomes**

#### **1**

##### **Description**

The maximum distance that patients walk during 6 minute walk test

##### **Timepoint**

At the initiation of the study and 3 months after vitamin D replacement

##### **Method of measurement**

There is a specialised corridor in department of pulmonary medicine where the distance passed by the patient can be measured on meter

### **Secondary outcomes**

#### **1**

##### **Description**

Perceived dyspnea during 6 minute walk test

##### **Timepoint**

At the initiation of study and three months after vitamin D replacement

##### **Method of measurement**

Visual analogue scale

#### **2**

##### **Description**

Forced expiratory volume in 1st second

##### **Timepoint**

at the initiation and three months after vitamin D replacement

##### **Method of measurement**

Spirometry

### **Intervention groups**

#### **1**

##### **Description**

Pearl Vitamin D 3 ,50,000 IU orally, weekly for 6 weeks

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Out patient Clinic of Pulmonary Diseases,Imam Khomeini hospital complex

###### **Full name of responsible person**

###### **Street address**

###### **City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mehrnaz Asadi Gharabaghi

**Street address**

Central official building, 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**

Mehrnaz Asadi Gharabaghi

**Position**

Assistant Professor, Respiratory Medicine Fellow

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*