

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

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Country

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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

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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