

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

A randomized clinical trial to compare the effect of vitamin D and placebo on FEV1 in patients with chronic obstructive pulmonary disease

Protocol summary

Summary

The main objective of this randomized clinical trial is to evaluate the effect of vitamin D on chronic obstructive lung diseases. Eighty patients with stable COPD who are suffering from concurrent vitamin D deficiency will be selected from those who are attending the outpatient clinic at Marvdasht hospital in 1395. Patients will be excluded if they have a history of TB, asthma, active cancer, diabetes, and any disease that affect vitamin D level. Forty patients will be randomly assigned to the intervention group (using a random permutation of numbers table) and will receive 50000 IU vitamin D, weekly for 10 weeks and the other group (control) will receive placebo weekly for 10 weeks (single-blinded). The outcome parameter will be FEV1 after 3 months. Both groups with all 4 stages of severity will be reassessed by FEV1 to show response to therapy. FEV1 above 80% will be marked as mild COPD, 50 to 79% will be moderate COPD, 30 to 49% as severe, and less than 30% as very severe COPD. All stages of COPD disease will be compared in intervention and control groups before and after vitamin D deficiency treatment. An improvement in the stage of severity of COPD will be considered as a significant improvement.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610306312N3**

Registration date: **2017-04-01, 1396/01/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-01, 1396/01/12

Registrant information

Name

Amir Anushiravani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1634 4292

Email address

anushirvan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-11-01, 1395/08/11

Expected recruitment end date

2017-01-31, 1395/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial to compare the effect of vitamin D and placebo on FEV1 in patients with chronic obstructive pulmonary disease

Public title

The effect of vitamin D on chronic obstructive pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Eighty cases of stable COPD with vitamin D deficiency. Exclusion criteria: past history of

TB; asthma; active cancer; diabetes; hypertension; ischemic heart disease; chronic kidney disease; liver failure; history of upper or lower respiratory tract infections; use of oral steroid within 1 month prior to study.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients will be randomly allocated in case and groups using a permutation of 20 numbers table. 0-4 will be placed in the case group and 5-9 in the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz, Iran

City

Shiraz

Postal code

7144

Approval date

2017-01-23, 1395/11/04

Ethics committee reference number

IR.SUMS.MED.REC.1395.65

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease, unspecified

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

FEV1

Timepoint

Beginning of study, 3 months later

Method of measurement

Pulmonary function test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients in this group will receive one oral 50000 IU pearl vitamin D3, weekly for 10 weeks.

Category

Treatment - Drugs

2

Description

Control group: patients in this group will receive one oral pearl, weekly for 10 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital and Clinic

Full name of responsible person

Amir Anushiravani

Street address

Motahari hospital and clinic, Moalem Square, Marvdasht

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

International Branch, Shiraz University of Medical Sciences

Full name of responsible person

Kamran Rasekh

Street address

Motahari Hospital, Moalem square, Marvdasht
City
 Marvdasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 International Branch, Shiraz 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
 International Branch, Shiraz University of Medical Sciences
Full name of responsible person
 Amir Anushiravani
Position
 Fellow in gastroenterology and hepatology
Other areas of specialty/work
Street address
 Department of Internal Medicine, Nemazee Hospital, Zand avenue, Shiraz
City
 Shiraz
Postal code
Phone
 +98 917 316 0616
Fax
Email
 amiranush23@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Shiraz University of Medical Sciences
Full name of responsible person

Amir Anushiravani
Position
 Fellow in Gastroenterology and Hepatology
Other areas of specialty/work
Street address
 Department of Internal Medicine, Nemazee Hospital, Zand Avenue, Shiraz
City
 Shiraz
Postal code
Phone
 +98 917 316 0616
Fax
Email
 amiranush23@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
 Shiraz University of Medical Sciences
Full name of responsible person
 Amir Anushiravani
Position
 Fellow in gastroenterology and hepatology
Other areas of specialty/work
Street address
 Department of Internal Medicine, Nemazee Hospital, Zand Avenue, Shiraz
City
Postal code
Phone
Fax
Email
 amiranush23@yahoo.com
Web page address

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