

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Study of the effect of vitamine D3 on incidence of exacerbations and infections of 'chronic obstructive pulmonary disease' patients (COPD) with serum levels of vitamine D less than 75 nmol/L.

Protocol summary

Summary

Objectives: 1. to define the effectiveness of supplementary vitamin D3 in lengthening time to COPD exacerbations. 2. to define the effect of supplementary vitamin D3 in lengthening of time to respiratory tract infection. Design: a randomized double blind clinical trial; the intervention group will receive vitamine D 50000 IU on a weekly basis on Saturdays after lunch and the placebo group will receive placebo on the same time schedule. The study is double blind, i.e. neither patients nor their physicians will know in which group the patients are. The primary outcome is the number of exacerbations, in addition time to exacerbation will be another evaluation variable. Inclusion criteria: All COPD patients including those with emphysema and chronic bronchitis with serum vitamin D-25 level less than 75 nmol/L. Exclusion criteria: 1. patients younger than 40 yrs; 2. patients with FEV1/FVC < 70%; 3. patients that after inhalation of 400 microgra salbutamol have FEV1/FVC > 70%; 4. patients with history of consumption of less than 15 pack year cigarettes; 5. patient with asthma or history of asthma; 6. patients with serum level of vitamine D > 75 nmol/L.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022826816N1**
Registration date: **2016-05-05, 1395/02/16**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

Shirin Izadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7742 8021

Email address

izadi.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-06-20, 1395/03/31

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of vitamine D3 on incidence of exacerbations and infections of 'chronic obstructive pulmonary disease' patients (COPD) with serum levels of vitamine D less than 75 nmol/L.

Public title

Prevention of COPD exacerbation by normalizing serum vitamin D3 level.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All COPD patients including those with emphysema and chronic bronchitis with serum vitamin D-25 level less than 75 nmol/L. Exclusion criteria: 1. patients younger than 40 yrs; 2. patients with FEV1/FVC < 70%; 3. patients that after inhalation of 400 micrograms salbutamol have FEV1/FVC > 70%; 4. patients with history of consumption of less than 15 pack year cigarettes; 5. patient with asthma or history of asthma; 6. patients with serum level of vitamin D > 75 nmol/L; 7. patients with diabetes, renal failure, history of MI, bronchiectasia, sarcoidosis, hypoparathyroidism, nephrolithiasis, active TB, liver failure, malignancy with remission less than 3 years ago; 8. patients under treatment with carbamazepine, cardiac glycosides, phenobarbital, phenytoin, perimidon; 9. patients with serum calcium level above 2.65 mmol/L or serum creatinine level above 125 micromol/L; 10. patients unable to cooperate with spirometry; 11. patient who need to receive more than 12 hrs per day oxygen.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee on Medical Research of Iran
University of Medical Sciences

Street address

Iran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2016-02-13, 1394/11/24

Ethics committee reference number

IR.IUMS.REC.1394.27529

Health conditions studied**1****Description of health condition studied**

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with acute exacerbation, unspecified

Primary outcomes**1****Description**

occurrence of an exacerbation of COPD

Timepoint

Monthly

Method of measurement

clinical and paraclinical observations

Secondary outcomes**1****Description**

functional class of the patients

Timepoint

End of the study

Method of measurement

clinical observation and interview

Intervention groups**1****Description**

Intervention: administration of Vitamin D3, Control: Placebo

Category

Treatment - Drugs

2**Description**

The control group (Placebo): This group will receive a placebo capsule after lunch on Saturday, each week for 12 consecutive weeks.

Category

Placebo

Recruitment centers**1****Recruitment center**

Name of recruitment center
Firoozgar General Hospital

Full name of responsible person

Shirin Izadi

Street address

Firoozgar General Hospital; Valiasr Ave.; Tehran;
I.R.Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shirin Izadi

Street address

Firoozgar General Hospital

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Shirin Izadi

Position

MD

Other areas of specialty/work

Street address

Firoozgar General Hospital

City

Tehran

Postal code

Phone

+98 21 7742 8021

Fax

Email

izadi.sh@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shirin Izadi

Position

Attending Professor

Other areas of specialty/work

Street address

Firoozgar General Hospital

City

Tehran

Postal code

Phone

+98 21 7742 8021

Fax

Email

izadi.sh@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shirin Izadi

Position

Attending Professor

Other areas of specialty/work

Street address

Firoozgar General Hospital

City

Tehran

Postal code

Phone

+98 21 7742 8021

Fax

Email

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