

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of vitamin D on recovery and quality of life of chronic obstructive pulmonary disease patients.

Protocol summary

Summary

Objectives : the main aim of this study is the effect of adding 25-hydroxy vitamin D to standard treatment of COPD patients on the improvement of recovery , quality of life and spirometry. Design : this study is double blind randomized clinical trial. Setting and conduct : in this study we register COPD patients referring to a pulmonary subspecialty clinic. Major eligibility criteria : the inclusion of study criteria are as following : the proof of COPD diagnosis according to clinical conditions and its approval with spirometry based on GOLD ; low serum levels of 25-hydroxyvitamin D (10-30) as insufficiency. The study exclusion criteria : hypercalcemia ; calcium more than 10.3 ; sarcoidosis (according to diagnosis and clinical examination of pulmonary subspecialty) ; cancer (asking the patient) ; osteoporosis that has recently been diagnosed (asking the patient) ; long term use of azithromycin (asking the patient) ; Serum 25-hydroxy vitamin D levels less than 10 as deficiency ; thyroid and parathyroid diseases. Intervention Patients chosen according to inclusion criteria were divided into two groups based on block randomization : one group was under the treatment with vitamin D supplement and another group received placebo , weekly (a tablet with IU 50000 pearl) for 2 months and monthly (a tablet with IU 50000 pearl) for 4 months. Main outcome measures are COPD recovery according to GOLD stage , evaluation of quality of life of patients , serum levels of 25-hydroxyvitamin D. The patients and information collectors are not informed of the study groups. Demographic characteristics of the patients including : age, gender, body mass index , smoking , lung function test and life quality questionnaire (CAT) are recorded in patients' information forms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072114085N2**

Registration date: **2014-03-11, 1392/12/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-11, 1392/12/20

Registrant information

Name

Ali Alavi

Name of organization / entity

Inflammatory Lung Disease Research Center, Razi Hospital, Gilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3354 2460

Email address

ali_alavi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

1-Vice chancellor of research ,Guilan University of Medical Sciences 2-Pharmaceutical company shafayab

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D on recovery and quality of life of

chronic obstructive pulmonary diseasepatients.		2013-01-01, 1391/10/12
Public title	The effect of vitamin D deficiency treatment on chronic obstructive pulmonary diseasepatients	Ethics committee reference number 1910354603
Purpose	Treatment	Health conditions studied
Inclusion/Exclusion criteria	The inclusion of study criteria are as following : the proof of COPD diagnosis according to clinical conditions and its approval with spirometry based on GOLD ; low serum levels of 25-hydroxyvitamin D (10-30) as insufficiency. The study exclusion criteria : hypercalcemia ; ca more than10.3 ; sarcoidosis (according to diagnosis and clinical examination of pulmonary subspecialty ; cancer (asking the patient) ; osteoprosis that has recently been diagnosed (asking the patient) ; long term use of azithromycin (asking the patient) ; serum 25-hydroxy vitamin D levels less than 10 as deficiency ; thyroid and parathyroid diseases.	1 Description of health condition studied Chronic Obstructive Pulmonary Disease ICD-10 code J44 ICD-10 code description Other chronic obstructive pulmonary disease
Age	No age limit	Primary outcomes
Gender	Both	1 Description The rate of change in COPD stage according to GOLD stages Timepoint The time of study inclusion and one month later and 6 months later. Method of measurement Spirometry
Phase	N/A	2 Description Evaluation of quality of life of patients Timepoint The time of study inclusion and one month later and 6 months later. Method of measurement CAT Questionnair
Groups that have been masked	No information	3 Description Serum levels of 25-hydroxyvitamin D Timepoint The time of study inclusion and one month later and 6 months later. Method of measurement Measurement of serum levels of 25-hydroxyvitamin D
Sample size	Target sample size: 50	Secondary outcomes
Randomization (investigator's opinion)	Randomized	1 Description Mortality Timepoint During study Method of measurement Recording in patients' information forms
Randomization description		2 Description
Blinding (investigator's opinion)	Double blinded	
Blinding description		
Placebo	Used	
Assignment	Parallel	
Other design features	patients and the person who collect data are not informed from study groups .	
Secondary Ids	empty	
Ethics committees		
1		
Ethics committee		
Name of ethics committee	Research Council of Guilan University of Medical Sciences	
Street address	gaz avenue- shahid beheshti street	
City	rasht	
Postal code		
Approval date		

The duration of taking Systemic steroids and antibiotics

Timepoint

During the study

Method of measurement

Recording in patients' information forms

3

Description

number of exacerbations

Timepoint

duringt study

Method of measurement

recording in patients' information forms

4

Description

The median time of the occurrence of the first exacerbation during the study

Timepoint

during study

Method of measurement

recording in patients' information forms

Intervention groups

1

Description

Vitamin D treatment group will take a pill with a dose of 50,000 IU for 2 months and then will take a pill monthly for 4 months.

Category

Treatment - Drugs

2

Description

Placebo treatment group will take a placebo pill for 2 months and then a vitamin D placebo pill monthly for 4 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pulmonary subspecialty clinic of Dr alavi

Full name of responsible person

Sara Massahnia

Street address

City

rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research ,Guilan University of Medical Sciences

Full name of responsible person

Dr abdolrasool sobhani

Street address

Gaz square-Vice chancellor of research ,Guilan University of Medical Sciences

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research ,Guilan 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

Respiratory Research Center of Guilan University Medical Sciences

Full name of responsible person

Sara Massahnia

Position

Manager of respiratory research center

Other areas of specialty/work

Street address

Razi hospital -Sardar jangal avenue-Rasht

City

Rasht

Postal code

41448-95655

Phone

+98 13 1554 2460

Fax

+98 13 1554 2460

Email

massahnias@yahoo.com : rrc@gums.ac.ir

Web page address

http://www.gums.ac.ir/rrc

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Respiratory Research Center of Guilan University
Medical Sciences

Full name of responsible person

Ali Alavi

Position

Pulmonologist

Other areas of specialty/work

Street address

razi hospital--sardar jangal avenue-rasht

City

Rasht

Postal code

41448-95655

Phone

+98 13 1554 2460

Fax

Email

aalavi_foumani@yahoo.comali_alavi@gums.ac.ir

Web page address

Position

Medical student

Other areas of specialty/work

Street address

Sardar jangal avenue-Razi hospital

City

Rasht

Postal code

41448-95655

Phone

+98 13 1554 2460

Fax

+98 13 1554 2460

Email

rrc@gums.ac.ir

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

Person responsible for updating data

Contact

Name of organization / entity

Respiratory Research Center of Guilan University
Medical Sciences

Full name of responsible person

Setare Alavi