Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

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

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 tril. 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 ; 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. 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
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Iran (Islamic Republic of)
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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.

Public title
The effect of vitamin D deficiency treatment on chronic obstructive pulmonary diseasepatients
Purpose
Treatment
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.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization 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
2013-01-01, 1391/10/12
Ethics committee reference number
1910354603

Health conditions studied

1

Description of health condition studied
Chronic Obstructive Pulmonary Disease
ICD-10 code
J44
ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

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

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

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

Secondary outcomes

1

Description
Mortality
Timepoint
During study
Method of measurement
Recording in patients’ information forms

2

Description

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

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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

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Person responsible for updating data

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Full name of responsible person
Setare Alavi

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Medical student

Other areas of specialty/work

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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