Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of different dose of vitamin D on vitamin D level in patients with severe chronic obstructive pulmonary disease based on GOLD criteria with vitamin D deficiency

Protocol summary

Study aim

Comparing the effect of different dose of vitamin D on level of vitamin D in patients with sever chronic obstructive pulmonary disease based on GOLD criteria and referred to Velayat hospital of Qazvin in year of 2018

Design

Clinical trial, with parallel groups, double-blind (patient and evaluator), randomized, phase 3 on 46 patients. To randomize, generate random numbers in the software.

Settings and conduct

Patients with severe chronic obstructive pulmonary disease who are referred to Velayat hospital of Qazvin, enter to the study after obtaining consent form. Spirometry test and their vitamin D levels are assessed according to the GOLD criteria. Then they are randomly divided into two groups with 23 cases. One group is treated with 4,000 units of vitamin D daily, and the other group is treated with 50,000 units of vitamin D a week for 12 weeks. Patient and evaluator are not aware of the type of treatment groups. Spirometry test and vitamin D levels are assessed again after 5 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient with sever chronic obstructive pulmonary disease, vitamin D deficiency (less than 30 nanogeram per milli liter). Exclusion criteria: History of advanced liver disease, history of advanced kidney disease, history of drug use (barbiturates, phenytoin and rifampin) during the last three months

Intervention groups

Treatment of vitamin D deficeincy with vitamin D 4000 unit daily for 12 week in intervention group and 50000 unit weekly for 12 week in control group

Main outcome variables

vitamin D level ; COPD severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180924041108N1**
Registration date: **2020-07-11, 1399/04/21**
Registration timing: **retrospective**

Last update: **2020-07-11, 1399/04/21**
Update count: **0**

Registration date

2020-07-11, 1399/04/21

Registrant information

Name

Maryam Qeraati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3379 0620

Email address

m.gharati@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of different dose of vitamin D on vitamin D level in patients with severe chronic obstructive pulmonary disease based on GOLD criteria with vitamin D deficiency

Public title
The effect of different doses of vitamin D on vitamin D levels in patients with severe chronic obstructive pulmonary disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
sever chronic obstructive pulmonery disease Vitamin D deficiency (less than 30 nanogram per milliliter)

Exclusion criteria:
History of advanced liver disease history of advanced kidney disease history of drug use (barbiturates, phenytoin and rifampin) during the last 3 months

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method is done as individually and using software. In the software, we generate random numbers between zero and one. For numbers less than 0.5, the person is placed in group A and for numbers greater than 0.5, the person is placed in group B.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences

Street address
No. 36, Norouzian Ave., Hekmat 62

City
Qazvin

Province
Qazvin

Postal code
3414744647

Approval date
2019-07-03, 1398/04/12

Ethics committee reference number
IR.QUMS.REC.1397.056

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease

ICD-10 code
J44.9

ICD-10 code description
Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description
level of vitamin D

Timepoint
At baseline and after 5 month

Method of measurement
labratory test

2

Description
severity of COPD

Timepoint
At baseline and after 5 month

Method of measurement
Spirometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: vitamin D 4000 unit daily for 12 week

Category
Treatment - Drugs

2

Description
Control group: vitamin D 50000 International unit weekly for 12 week

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
velayat hospital
Full name of responsible person
Mona Babaie
Street address
No36,Hekmat 62. Noruzian Avenue
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qazvin
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3414744647
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moba_415@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mahnaz Abbasi
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Elahie Ave., 22 bahman Blvd. Tavon Sqr
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Ali32024@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
-

Proportion provided by this source
1

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mona Babaie
Position
Internal medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available