

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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 nanogram 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

**City**

qazvin

**Province**

Qazvin

**Postal code**

3414744647

**Phone**

+98 28 3367 1552

**Email**

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

**Street address**

Elahie Ave., 22 bahman Blvd. Tavon Sqr

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**Phone**

+98 28 3379 0620

**Email**

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**

Internal Medicine

**Street address**

No36,Hekmat 62. Noruzian Avenue

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Mona Babaie

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Mona Babaie

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

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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