# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 2026

## effectiveness of vitamin D supplementation in quality of life of patients with chronic obstructive pulmonary disease and vitamin D deficiency

## Protocol summary

**Study aim**
Increasing the quality of life of chronic obstructive pulmonary disease

**Design**
Both common treatment groups receive COPD. In addition to the usual treatment, both the case and control groups receive 1000 units of oral Nano D3 capsules daily for 8 weeks.

**Settings and conduct**
COPD patients have been diagnosed with spirometry using FEV1 and FVC by a pulmonary specialist at Khatam al-Anbia Clinic, and have completed other criteria for entering the study and will enter the study.

**Participants/Inclusion and exclusion criteria**
Moderate to severe COPD patients

**Intervention groups**
One group receives vitamin D in addition to the usual COPD treatment, and the other group receives medication.

**Main outcome variables**
FEV1 و FVC

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190810044500N12**
Registration date: **2021-05-06, 1400/02/16**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-06, 1400/02/16**
Update count: **0**

**Registration date**
2021-05-06, 1400/02/16

**Registrant information**

**Name**
Fatemeh Saghafi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 35 3820 3419

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-05-05, 1400/02/15

**Expected recruitment end date**
2021-11-06, 1400/08/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
effectiveness of vitamin D supplementation in quality of life of patients with chronic obstructive pulmonary disease and vitamin D deficiency

**Public title**
effectiveness of vitamin D in COPD

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Moderate to severe COPD patients Vitamin D level less than 20ng/ml age more than 18

**Exclusion criteria:**
age less than 18 years Vitamin D level more than 20ng/ml Mild COPD patients patients with COPD exacerbation pregnancy lactation

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were randomly assigned to two groups of 15 controls or intervention by the permutation block method. Treatment assignments within blocks are determined so that they are random in order but that the desired allocation proportions are achieved exactly within each block. 10 blocks of 4 are considered. Generation of random codes using Permuted Block Randomization method will be done with the help of Random allocation software (version 1). The first person who is eligible to enter the study is given number one and likewise, the last eligible person is given number 30. By using the software-generated table, patients receive each intervention (A or B). In order to consider blinding in random allocation, the list is given to another person outside the study and using short message service (SMS) before assigning the type of treatment according to the number of eligible people is asked and thus people enter the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Blinding has been done on people evaluating variables and data analysts

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of faculty of medicine, Shahid sadoughi university of medical sciences

**Street address**

Shahid Sadoughi University of Medical Scienes, Shohada gomnam Blvd, Yazd

**City**

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**Province**

Yazd

**Postal code**

8915173143

**Approval date**

2020-11-10, 1399/08/20

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1399.169

## 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**

Percentage of people with chronic obstructive pulmonary disease

**Timepoint**

Before the start of the intervention and in the 2nd and 4th month of the start of treatment and after the end of treatment

**Method of measurement**

Blood sample

## Secondary outcomes

### 1

**Description**

Quality of Life

**Timepoint**

Before the start of the intervention and in the 2nd and 4th month of the start of treatment and after the end of treatment

**Method of measurement**

questionnaire ( EORTC QLQ - C30 version 3)

## Intervention groups

### 1

**Description**

Intervention group: Receive 1000 IU of Vitamin D3 capsule daily for 8 weeks

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Receive placebo of oral Vitamin D3 1000 capsule daily for 8 weeks

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Khatam Al-Anbia Clinic
**Full name of responsible person**
Dr. Mohsen Gholi Netaj
**Street address**
Motehari street
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Yazd University of Medical Sciences
**Full name of responsible person**
Mohammad Reza Mirjalili
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Yazd University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Private
**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**
Yazd University of Medical Sciences
**Full name of responsible person**
Fatemeh Saghafi
**Position**
Assistant Professor
**Latest degree**
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**Other areas of specialty/work**
Medical Pharmacy
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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