

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 , 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

Email address

f.saghafi@ssu.ac.ir

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 Sciences, Shohada gomnam Blvd, Yazd

City

Yazd

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

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam Al-Anbia Clinic
Full name of responsible person
Dr. Mohsen Gholi Netaj
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
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ravabet@ssu.ac.ir
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

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Fatemeh Saghafi
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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