Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Fatemeh Saghafi
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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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
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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
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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