

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effectiveness of Vitamin D Supplementation in Quality of Life of patient with severe and very severe Chronic Obstructive Pulmonary Disease with serum levels of Vitamin D less than 20ng/ml compared with the control group

Protocol summary

Summary

The main aim of current study is to define the effectiveness of vitamin D supplement in quality of life of patients with severe and very severe chronic obstructive pulmonary disease with Vitamin D Deficiency. A randomized double blind clinical trial that will be randomized in two groups (intervention and control) based on blocked randomization. In this study 84 patients will participate. The intervention group (42 patients) will receive vitamin D and the control group (42 patients) will receive placebo. Neither patients nor their physicians will know in which group the patients are. The inclusion criteria of the study are as the following: Patients with vitamin level less than 20 nano gram per milliliter; age more than 40. The study exclusion criteria: Patients who receive vitamin d supplementation more than 400 unit per day ; Taking daily dose of systemic corticosteroid(oral or injection) as maintenance. the Intervention group will receive vitamin D3 as an oral pearl (50,000 IU) weekly for 8 weeks and then they will continue the treatment every two weeks for 4 months. In the control group, patients will receive placebo on the same time schedule. The primary outcome is to improve the quality of life which measures by SGRQ-C, m-MRC, and CAT, first exacerbation of COPD, and serum level of vitamin D3.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021030705N1**
Registration date: **2017-02-10, 1395/11/22**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

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Name of organization / entity

North Khorasan University of Medical Science

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Recruitment status

Recruitment complete

Funding source

North Khorasan University of Medical Sciences, Bojnourd, Iran

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

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 patient with severe and very severe Chronic Obstructive Pulmonary Disease with serum levels of Vitamin D less than 20ng/ml compared with the control

group

Public title

Vitamin D efficacy on COPD

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients with vitamin level more than 20 nano gram per milli liter; age more than 40; patients with diagnosis of severe and very severe COPD; patients who complete the consent form
Exclusion criteria: Patient who receive vitamin D supplementation more than 400 unit per day; taking daily dose of systemic corticosteroid(oral or injection) as maintenance; personal history of one of the following diseases: Osteoporosis, Asthma, renal failure, liver failure, Nephrolithiasis, Hypercalcemia, active TB, Malignancy, Sarcoidosis, Malabsorption; pregnancy and lactation or individuals who want to be pregnant during the study; using of antileptic drugs(barbitorat and phenytoin,) and alcohol; patient with psychological problem; unreliable patients in study.

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of North Khorasan University of Medical Science

Street address

No36,Shahid Mohaghar sreet, Shahid Beheshty Avenue, bojnourd, iran

City

Bojnourd

Postal code

Approval date

2016-07-31, 1395/05/10

Ethics committee reference number

ir.nkums.REC.1395.51

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease (COPD)

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Evaluation of quality of life

Timepoint

At time of inclusion, 1, 3, and 6 months after treatment

Method of measurement

m-MRC Questionnaire

2

Description

The time of first acute exacerbation

Timepoint

During the study

Method of measurement

Recording in the patients' information form

3

Description

Evaluation of quality of life

Timepoint

At time of inclusion, 1, 3, and 6 months after treatment

Method of measurement

SGQR-C Questionnaire

4

Description

Evaluation of quality of life

Timepoint

At time of inclusion, 1, 3, and 6 months after treatment

Method of measurement

CAT Questionnaire

Secondary outcomes

1

Description

The number of hospitalization

Timepoint

During the study

Method of measurement

Recording in the patients' information form

2

Description

Length of stay

Timepoint

During the study

Method of measurement

Recording in the patients' information form

3

Description

Serum level of 25-hydroxyvitamin D

Timepoint

At time of inclusion, 1, 3, and 6 months after treatment

Method of measurement

Measurement of serum level

Intervention groups

1

Description

Intervention group: Patients in this group will take oral pearl Vitamin D3 (50,000 IU) weekly for 8 weeks. Then, They receive this dose of Vitamin D3 every two weeks for 4 months (Totally 16 doses).

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will take a placebo exactly the same as the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

North Khorasan University of Medical Sciences

Full name of responsible person

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

North Khorasan University of Medical Sciences

Full name of responsible person

Alireza Golshan

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No36,Shahid Mohaghar sreet, Shahid Beheshti Avenue, boujnourd. North Khorasan,Iran

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Bojnourd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

North Khorasan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty