Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 corticosterioid(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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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 ingection) 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
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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