

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effect of vitamin D and placebo on clinical and spirometric indices in patients with chronic obstructive pulmonary disease (COPD).

Protocol summary

Summary

The aim of this study (a clinical trial) is evaluating the effect of vitamin D deficiency treatment on relieving the clinical Symptoms and spirometric indices in patients suffering from COPD. Sixty patients who are suffering from COPD and vitamin D deficiency (less than 30ng/dl), are 30-80 years old enter the research based on inclusion Criteria. These patients are selected from lung clinic in Valiasr hospital. Then Patients are divided to 2 group and each group have 30 patients through simple random sampling method. In First group (drug group), one 50000 IU purl of vitamin D, every week for 3 continuous months and one calcium-D tablet daily will be prescribed in addition to standard COPD treatment. Second group (placebo group) will receive placebo, every week for 3 months in addition to standard COPD treatment. At the beginning and after 3 months, the spirometry process and measurement of 25 OH vitamin D, Calcium (ca), Phosphorus (p), Albumin and Parathyroid Hormone (PTH) will be performed for all patients. Every month Patients will be controlled from the perspective of drug consumption and correct using of it and they will be excluded if the exclusion criteria met (renal disease, liver disease, parathyroid disease, malnutrition, malabsorption). In this study, increase of Forced expiratory volume during the first second (FEV1), Forced expiratory volume during the first second / Forced Vital Capacity (FEV1/FVC) and 25 (OH) Vit D in first group compared to second group as a primary consequence and reduction of Dyspnea severity based on MRC criteria in first group compared to second group, will be discussed as secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042919554N12**

Registration date: **2017-10-27, 1396/08/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-27, 1396/08/05

Registrant information

Name

Maryam Jameshorani

Name of organization / entity

Zanjan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan University of Medical Sciences.

Expected recruitment start date

2016-07-20, 1395/04/30

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vitamin D and placebo on clinical and spirometric indices in patients with chronic obstructive pulmonary disease (COPD).

Public title

The effect of vitamin D deficiency treatment on dyspnea severity in patients with COPD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Outpatients suffering from COPD who haven't had COPD exacerbation in last 2 weeks; serum vitamin D level less than 30 ng / dl; written consent for participating in the study. Exclusion Criteria: liver problems (LFT equal to or more than 2 times more than normal); renal failure (GFR<60); Granulomatous diseases (including tuberculosis, sarcoidosis); malnutrition; malabsorption (including IBD and Celiac); any types of cancer; parathyroid disease.

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

the patients categorized non-randomly into groups treated with vitamin D (with the assignment of zero and even numbers) and placebo (by assigning individual numbers).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Karmandan street, Zanjan

City

Zanjan

Postal code

4415777978

Approval date

2016-11-23, 1395/09/03

Ethics committee reference number

ZUMS.REC.1395.202

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J43, J44.8

ICD-10 code description

Emphysema -Other specified chronic obstructive pulmonary disease-Chronic obstructive pulmonary disease, unspecified- -

Primary outcomes

1

Description

Forced expiratory volume (FEV1)

Timepoint

Before the intervention and three months after the end of intervention

Method of measurement

spirometry

2

Description

Forced expiratory volume 1/ Forced vital capacity(FEV1/FVC)

Timepoint

Before the intervention and three months after the end of intervention

Method of measurement

Spirometry

Secondary outcomes

1

Description

severity of Dyspnea

Timepoint

Before the intervention and three months after the end of intervention

Method of measurement

MRC Dyspnoea Scale

2

Description

Weight

Timepoint

Before the intervention and three months after the end of intervention

Method of measurement

Scale

Intervention groups**1****Description**

Intervention group: 50000 IU Pearl vitamin D every week and 500mg calcium-D tablet daily (for three month)

Category

Treatment - Drugs

2**Description**

Control group: Perl placebo every week and calcium-D 500 mg tablets daily (for three months)

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Respiratory clinic, Vali-Asr Hospital

Full name of responsible person

Maryam Jameshorani

Street address

Valiasr hospital, Valiasr Sq, Zanjan

City

Zanjan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Zanjan University of Medical Sciences.

Full name of responsible person

Alireza Shoghli.

Street address

Zanjan University of Medical Sciences, Karmandan street, Zanjan

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Zanjan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Maryam Jameshorani

Position

Internal medicine specialist, Assistant Professor of University

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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