Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial for comparing the effect of 25(oh)2vitD, calcitriol and placebo on pulmonary function test, serum C reactive protein and total antioxidant in patient with chronic obstructive pulmonary disease.

Protocol summary

Summary

Chronic obstructive pulmonary disease (COPD) is a heterogeneous, multi-component disease which is a leading public health concern worldwide.Patients with COPD are prone to exacerbation that are an important determinant of health-related quality of life, morbidity and mortality . Few studies have reported on 25-OHD serum levels in COPD patients. Lower vitamin D status in African Americans correlates with an increased susceptibility to COPD . We designed a double blind randomized controlled trial to assess the role of exogenous supplementation of vitamin D and calcitriol or placebo on lung function , CRP level and systemic oxidant antioxidant levels, in the patients with COPD. In this study 120 patient with COPD exacerbation randomly divides to 3 groups .All patients should have no other significant disease .Patients receives 50000 unit 25(oh)2vitD or 25 µg calcitriol or seasame oil as placebo for 7 days and at first and 8th day pulmonary function test and serum Creative protein and total anti oxidant will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138712271774N1**
Registration date: **2011-04-10, 1390/01/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-10, 1390/01/21

Registrant information

Name

Mojgan Sanjari

Name of organization / entity

Kerman University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences, Physiology Research center of Kerman university of medical sciences and Endocrine research center of Tehran university of medical sciences

Expected recruitment start date

2009-02-20, 1387/12/02

Expected recruitment end date

2010-01-21, 1388/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial for comparing the effect of 25(oh)2vitD, calcitriol and placebo on pulmonary function test, serum C reactive protein and total antioxidant in patient with chronic obstructive pulmonary disease.

Public title

Vitamin D and COPD

Purpose

Treatment

Inclusion/Exclusion criteria

Including criteria: 1.Having COPD exacerbation 2.Age between 40 and 60 years 3.Moderate to severe disease. Exclusion criteria 1.Unwillingness to participate in the study, 2.Unable to perform spirometry, 3.History of any other respiratory disorder including asthma , bronchial carcinoma,lower respiratory tract infection 4. Recent (within 4 wk) hospitalization for COPD, 6.Any medical condition which needed more invasive respiratory support,6.Evidence of hypercalcemia, renal failure, hyperparathyroidism, malignancy, history of renal stone, cardiac arrhythmia, or patients who were using lithium.

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

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 kerman university of medical sciences

Street address
jomhoori BLVD,central office of kerman university of medical sciences

City
kerman

Postal code
7618747653

Approval date
2009-06-18, 1388/03/28

Ethics committee reference number
17/88

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease, unspecified

ICD-10 code
J44.9

ICD-10 code description
Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description
25(OH)2vit D3

Timepoint
first and 8th day

Method of measurement
Enzyme assay

2

Description
1,25(oh)2vitD3

Timepoint
first and 8th day

Method of measurement
Enzyme assay

3

Description
FEV1 and FVC

Timepoint
8th day

Method of measurement
spirometry

Secondary outcomes

1

Description
C Reactive Protein,CRP

Timepoint
first and 8th day

Method of measurement
latex-enhanced immunoturbidimetric assay

2

Description
Serum Total Antioxidant

Timepoint
first and 8th day

Method of measurement
Calorimetry

Intervention groups

1

Description
Group A(Placebo): Patients receives standard treatment for COPD as recommended by the GOLD guidelines plus placebo capsule (sesame oil), similar in appearance to active drug in group B and C, one capsule daily for a week.
Category
Placebo

2

Description
Group B: Patients receives standard treatment for COPD as recommended by the GOLD guidelines plus vitamin D ,25 (OH)-D3 (Pourateb, Iran) 50000 IU, one capsule daily for a week.
Category
Treatment - Drugs

3

Description
Group C: Patients receives standard treatment for COPD as recommended by the GOLD guidelines plus Calcitriol, 1, 25 (OH)2-D3 (Pourateb, Iran) 0.25 µg, one capsule daily for a week.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour hospital ,kerman Iran
Full name of responsible person
Dr. Maryam Zareinejad
Street address
pulmonary ward and internal medicine emergency room-afzalipour hospital-Kerman-Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences PhYsiology resaerch center of
Full name of responsible person
Dr.Hamid Najafi pour,
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Physiology research center, Ebne sina Ave, Jahad Blvd, Kerman, Iran
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Grant name
Grant code / Reference number
88/58
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kerman University of Medical Sciences PhYsiology resaerch center of
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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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