

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 sesame 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

Iran (Islamic Republic of)

##### Phone

+98 34 1322 2506

##### Email address

msanjari@kmu.ac.ir

##### 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

#### City

Kerman

## 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,

#### Street address

Physiology research center, Ebne sina Ave, Jahad Blvd, Kerman, Iran

#### City

Kerman

#### 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

Kerman university of Medical sciences

#### Full name of responsible person

Dr. Mojgan Sanjari

#### Position

Assistant professor

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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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*