

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation of Effects Oral Supplements Vitamine D on COPD Exacerbation and FEV1 in Patients With Severe and Very Severe COPD

#### Protocol summary

##### Summary

randomised/double blind/case-control/control without placebo Inclusion criteria:chronic obstructive pulmonary diseases patients with FEV1/FVC<0/7 and FEV1<50%;negative past medical history of vitamins D disorders exclusion criteria:positive past medical history of vitamins D disorders target sample size:88 patients in case group have intervated with oral agents vitamineD(in 6 months with doses100000internationalunits of vitamine D3 monthly within 6months)and routin drugthrapy for choronic obstructive pulmonary diseases .patients in control group have treatment wiyh routin drugs for choronic obstructive pulmonary diseases. duration of intervention:1390/12/15-1391/07/15

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012071810332N1**  
Registration date: **2012-08-07, 1391/05/17**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-08-07, 1391/05/17

##### Registrant information

##### Name

Elham Senisel bachari

##### Name of organization / entity

Khorrabadmedical university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 916 333 3143

##### Email address

eli2shim@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Khorrabad University Of Medical Sciences

##### Expected recruitment start date

2012-03-05, 1390/12/15

##### Expected recruitment end date

2012-10-06, 1391/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Effects Oral Supplements Vitamine D on COPD Exacerbation and FEV1 in Patients With Severe and Very Severe COPD

##### Public title

Effects Oral Agents Vitamine D On COPD

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusioncriteria:COPD patients with FEV1/FVC<0/7 and FEV1<50%;negative past medical history of vitamins D disorders exclusion criteria:positive past medical history of vitamins D disorders

##### Age

No age limit

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

## Sample size

Target sample size: **88**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Khorramabad University Of Medical Sciences

##### Street address

Pardis departmen, Kamalvand region, Khorramabad, Lorestan

##### City

Khorramabad

##### Postal code

#### Approval date

2012-06-10, 1391/03/21

#### Ethics committee reference number

1280

## Health conditions studied

### 1

#### Description of health condition studied

Severe and very severe COPD

#### ICD-10 code

J44

#### ICD-10 code description

Chronic obstructive pulmonary diseases

### 2

#### Description of health condition studied

Added at 2012-08-07: chronic obstructive pulmonary diseases

#### ICD-10 code

Added at 2

#### ICD-10 code description

Added at 2012-08-07:

## Primary outcomes

### 1

#### Description

FEV1

#### Timepoint

Before intervention and after intervention

#### Method of measurement

Spirometry(PFT)

## Secondary outcomes

### 1

#### Description

COPD Exacerbation

#### Timepoint

Before and mean and afterof intervention

#### Method of measurement

Physical exam

## Intervention groups

### 1

#### Description

patients in case group have intervened with oral agents vitamineD(in 6 months with doses100000internationalunits of vitamin D3 monthly within 6months)and routin drugthrapy for Chronic obstructive pulmonary diseases.patients

#### Category

Prevention

### 2

#### Description

in control group have treatment with routine drugs for Chronic obstructive pulmonary diseases

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khorramabad Shohadaye Ashayer Hospital

##### Full name of responsible person

##### Street address

##### City

Khorramabad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Khorramabad Univercity Of Medical Sciences

##### Full name of responsible person

Doktor Qolamreza Kayedi

##### Street address

Pardis department, Kamalvand region, Khorramabad,

Lorestan

**City**

Khorramabad

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Khorramabad 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**

Khorramabad University Of Medical Sciences

**Full name of responsible person**

Doktor Abolphazl Zendedel

**Position**

Chief of Khorramabad University Of Medical Sciences

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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*