

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