

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of vitamin D in the improvement of pulmonary function tests in patients with chronic obstructive pulmonary disease

Protocol summary

Summary

Inclusion criteria; All eligible patients with chronic obstructive pulmonary diseases(COPD) will be included to study . Exclusion criteria; Patients with chronic pulmonary infections ,restrictive airway diseases,cor pulmonale,congestive heart failure,pulmonary emboli neoplasia,occupational lung disease and pregnant women will be excluded Intervention; Patients will take 50.000 IU oral vitamin D3 weekly in addition to their usual treatment regimen.Controls group take in addition to the usual drug and in the remaining 30 patients placebo will be added to their usual drugs Primary outcome; Mean differences in FEV1,FVC,FEV1/FVC,from baseline after 3 and six months Secondary outcome;Proportions of patients responded to the treatment (defined as 20% improvement in FEV1 absolute value in ml compared with baseline values) in treatment group compared with placebo group

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103154724N2**

Registration date: **2011-07-24, 1390/05/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-24, 1390/05/02

Registrant information

Name

Mahmood Monadi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 8284

Email address

drmonadi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research ,Babol university of medical sciences

Expected recruitment start date

2011-06-21, 1390/03/31

Expected recruitment end date

2011-12-23, 1390/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of vitamin D in the improvement of pulmonary function tests in patients with chronic obstructive pulmonary disease

Public title

Vitamin D and airway obstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : All eligible patients with chronic obstructive pulmonary diseases(COPD) will be included to study. Exclusion criteria :Patients with chronic pulmonary infections ;restrictive airway diseases;cor pulmonale;congestive heart failure;pulmonary emboli neoplasia;occupational lung disease and pregnant women will be excluded .

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee Babol university of medical science

Street address

Rohani hospital, Keshavarz Blvd, University Sq

City

Babol

Postal code

4717641367

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

8928513

Health conditions studied**1****Description of health condition studied**

COPD patients

ICD-10 code

J40

ICD-10 code description

Bronchitis, not specified as acute or chronic

2**Description of health condition studied**

COPD

ICD-10 code

J41

ICD-10 code description

Simple and mucopurulent chronic bronchitis

3**Description of health condition studied**

COPD

ICD-10 code

J42

ICD-10 code description

Unspecified chronic bronchitis

4**Description of health condition studied**

COPD

ICD-10 code

J43

ICD-10 code description

Emphysema

5**Description of health condition studied**

COPD

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

6**Description of health condition studied**

COPD

ICD-10 code

J45

ICD-10 code description

Asthma

7**Description of health condition studied**

COPD

ICD-10 code

J46

ICD-10 code description

Status asthmaticus

8**Description of health condition studied**

COPD

ICD-10 code

J47

ICD-10 code description

Bronchiectasis

Primary outcomes

1

Description

Mean differences in FEV1,FVC,FEV1/FVC,from baseline after 3 and six months

Timepoint

3 months and 6 months interval

Method of measurement

Pulmonary function test (PFT)

Secondary outcomes

1

Description

Proportions of patients responded to the treatment (defined as 20% improvement in FEV1 absolute value in ml compared with baseline values) in treatment group compared with placebo group

Timepoint

After 3 months and 6 months of treatment

Method of measurement

PFT

Intervention groups

1

Description

30 patients will take 50.000 IU oral vitamin D3 weekly in addition to their usual treatment regimen of vitamin D will be adjusted over the study period to maintain serum 25-hydroxyvitamin D levels at 30-70 ng/ml by extending the dosage interval from one to 4 weeks .

Category

Treatment - Drugs

2

Description

The control group receives placebo in addition to their usual drugs

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouhani hospital

Full name of responsible person

Behzad Heidari MD

Street address

Rouhani haspital, Danesgah Square, Ganjafrooz Avenue, Babol

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- chancellor of Researcher Babol university of medical sciences

Full name of responsible person

Dr Amrolah Mostafazadeh

Street address

Vice- chancellor of Researcher, Ganjafrooz Avenue, Daneshgah Square, Babol

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice- chancellor of Researcher Babol 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

Babol University of Medical Sciences

Full name of responsible person

Behzad Heidari MD

Position

Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahmood Monadi MD

Position

Pulmologist

Other areas of specialty/work**Street address**

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Dr.monadi@yahoo.com

Web page address**Full name of responsible person**

Masoumeh Asgharpour MD

Position

Medical resident

Other areas of specialty/work**Street address**

Rohani hospital

City**Postal code****Phone****Fax****Email****Web page address**

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

Person responsible for updating data

Contact

Name of organization / entity

Babol university of medical sciences