Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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 comittee 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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Rouhani haspital, Danesgah Square, Ganjafrooz Avenue, Babol
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Mahmood Monadi MD

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Pulmologist

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Person responsible for updating data

Contact

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Babol university of medical sciences

Full name of responsible person
Masoumeh Asgharpour MD

Position
Medical resident

Other areas of specialty/work

Street address
Rohani hospital

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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