

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 hospital, 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

#### Street address

Rouhani hospital, Danesgah Square, Ganjafrooz Avenue, Babol

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#### Postal code

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#### Phone

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#### Email

heidaribeh@yahoo.com

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Babol university of medical sciences

**Full name of responsible person**

Mahmood Monadi MD

**Position**

Pulmologist

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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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

**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*