

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effect of supplementation of vitamin D, C and E on the lung functional tests, level of hs-CRP, ESR, TGF β 1 and antioxidant status in Idiopathic Pulmonary Fibrosis patients

Protocol summary

Summary

This study carried out in patient with pulmonary fibrosis and the aim of it is finding the effect of supplementation of vitamin E, C and D on lung tissue and its function moreover evaluating changes in biomedical and inflammatory factors. Patients with pulmonary fibrosis who passed more than six months of their disease and are not using another supplements will be enrolled in the study. If supplement consumption be less than 80% or having unwillingness to continue the participation they will be excluded from the study. The number of participants are 36 persons, in one group for intervention. Who will get daily dose of 200 IU of vitamin E, 250 mg of vitamin C for every other day for 12weeks, and weekly 50000 IU dose of vitamin D for 8 weeks and one another for 12th week. Pulmonary tests will evaluate lung functions, for measurement of forced expiratory volume in the first second as a primary outcome and also forced vital capacity, total lung capacity, inspiratory and expiratory reserve volume will be dumped for lung function assessment. Inflammatory parameters like Erythrocyte sedimentation rate, concentration of High-sensitivity c-reactive protein and Transforming growth factor β 1 will be measured. As well as antioxidant factors such as glutathione peroxidase and concentration of protein carbonyl will be examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612202365N15**

Registration date: **2017-01-07, 1395/10/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-07, 1395/10/18

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supplementation of vitamin D, C and E on the lung functional tests, level of hs-CRP, ESR, TGF β 1 and antioxidant status in Idiopathic Pulmonary Fibrosis patients

Public title

Effect of vitamin supplementation on pulmonary fibrosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Adults (20 years<) with idiopathic pulmonary fibrosis and according to the guidelines of Thoracic Society United States of America and Respiratory Health Association of Europe and final confirmation of respiratory disease physician, patients diagnosed for more than 6 months; Both sex; Avoiding the use of vitamin supplements Exclusion criteria: Unwillingness of individuals to continue participating in the study; Admission supplement inadequate (less than 80% of supplements)

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemat highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-11-19, 1395/08/29

Ethics committee reference number

IR.IUMS.REC1395.9411323008

Health conditions studied

1

Description of health condition studied

pulmonary fibrosis

ICD-10 code

J84.1

ICD-10 code description

Other interstitial pulmonary diseases with fibrosis

Primary outcomes

1

Description

percent of Forced Expiratory Volume in First Second FEV1

Timepoint

before intervention and 3 month after starting the intervention

Method of measurement

spirometry

Secondary outcomes

1

Description

Transforming growth factor β 1

Timepoint

Before intervention and 3 month after intervention

Method of measurement

measurement kit

2

Description

Inspiratory Reserve volume

Timepoint

Before intervention and 3 month after intervention

Method of measurement

spirometry

3

Description

Expiratory Reserve Volume

Timepoint

Before intervention and 3 month after intervention

Method of measurement

spirometry

4

Description

Protein carbonyls

Timepoint

Before intervention and 3 month after intervention

Method of measurement

measurement kit

5

Description

Residual Volume

Timepoint

Before intervention and 3 month after intervention

Method of measurement

spirometry

6

Description

Tidal Volume

Timepoint

Before intervention and 3 month after intervention

Method of measurement

spirometry

7

Description

High-sensitivity c-reactive protein

Timepoint

Before intervention and 3 month after intervention

Method of measurement

measurement kit

8

Description

Erythrocyte sedimentation rate

Timepoint

Before intervention and 3 month after intervention

Method of measurement

measurement kit

Intervention groups

1

Description

Participants will get a daily supplement of vitamin E with 200 IU dosage, vitamin C supplement with 250 mg dose every other day and 50000 IU of vitamin D once a week and for 8 weeks and another one in 12th week of study

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences

Full name of responsible person

Mohammadreza Vafa

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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University Research Assistant, Headquarter Bulding, Iran University Of Medical Sciences, Beside Milad hospital, Shahid Hemat high way, Tehran, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

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Professor

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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