

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of vitamin D supplementation and aerobic exercise on serum levels of inflammatory factors and lung function in male smokers

#### Protocol summary

##### Study aim

The effect of vitamin D supplementation and aerobic exercise on serum concentrations of inflammatory factors and pulmonary function in male smokers

##### Design

The study was a phase 2, community-based and pragmatic, randomized, no blinding, controlled clinical trial on 40 subjects, and a sealed envelope was used for randomization.

##### Settings and conduct

The subjects of the vitamin D supplement + aerobic exercise group and the aerobic exercise group ran for 4 weeks (3 days a week) with an intensity of more than 50% of the maximum heart rate in Tabriz Stadium. In addition, subjects in the vitamin D supplement group + aerobic exercise and the vitamin D supplement group received vitamin D 1000 units per week for four weeks. Also, the control group did not have any activity or supplementation during 4 weeks of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: having at least one year of smoking history and being healthy. Exclusion criteria: having clinical diseases

##### Intervention groups

Intervention group: 10 male smokers who did aerobic exercise for 4 weeks (running at more than 50% of maximum heart rate, 3 days a week) and at the same time taking vitamin D supplement (6000 units per week).  
Intervention group: 10 male smokers who did aerobic exercise for 4 weeks (running at more than 50% of maximum maximum heart rate, 3 days a week).  
Intervention group: 10 male smokers who took vitamin D supplement (6000 units per week) for 4 weeks. Control group: did not have any activity or supplementation during 4 weeks of intervention.

##### Main outcome variables

Tumor necrosis factor alpha (TNF- $\alpha$ ), Interleukin-6 (IL-6), Clara protein (CC16), Surfactant-D protein (SP-D) and Lung function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180513039637N4**

Registration date: **2020-10-20, 1399/07/29**

Registration timing: **retrospective**

Last update: **2020-10-20, 1399/07/29**

Update count: **0**

##### Registration date

2020-10-20, 1399/07/29

##### Registrant information

##### Name

Hadi Pourmanaf

##### Name of organization / entity

Tehran University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3656 1262

##### Email address

hadi.pvrmanaf@ut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-10, 1399/06/20

##### Expected recruitment end date

2020-10-11, 1399/07/20

##### Actual recruitment start date

2020-09-10, 1399/06/20

##### Actual recruitment end date

2020-10-11, 1399/07/20

##### Trial completion date

2020-10-11, 1399/07/20

## Scientific title

The effect of vitamin D supplementation and aerobic exercise on serum levels of inflammatory factors and lung function in male smokers

## Public title

The effect of vitamin D supplementation and aerobic exercise on inflammation and lung function in male smokers

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Have at least one year of smoking history Being male Healthy

### Exclusion criteria:

Having a history of diabetes Having a history of cardiovascular disease Having food allergies Having a history of respiratory disease Use a sports supplement before or during the study Use the drug before or during the study Use of inflammatory agents before or during the study

## Age

From **24 years** old to **38 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

Actual sample size reached: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Using simple randomization, individuals were divided into 4 homogeneous groups (endurance training + vitamin D, endurance training, vitamin D and control). The randomization tool was also sealed in the envelope. The randomization unit was also individual. Number 1 in the envelope showed the subjects in the endurance training group + vitamin D, number 2 showed the endurance training group, number 3 showed the training group of vitamin D and number 4 showed the control group. And there was no concealment.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Iran National Committee for Ethics in Biomedical Research

#### Street address

Iran National Committee for Ethics in Biomedical Research, Iran TV Street., Qods Town

#### City

Tehran

#### Province

Tehran

#### Postal code

0000000000

#### Approval date

2020-10-12, 1399/07/21

#### Ethics committee reference number

IR.TBZMED.REC.1399.727

## Health conditions studied

## 1

### Description of health condition studied

Dose not apply

### ICD-10 code

### ICD-10 code description

## Primary outcomes

## 1

### Description

Serum levels of interleukin 6 (IL-6) in male smokers

### Timepoint

Blood sampling one day before the intervention and 24 hours after the intervention (2 stages)

### Method of measurement

Interleukin6 Kit

## 2

### Description

Serum Tumor necrosis factor alpha (TNF- $\alpha$ ) levels in male smokers

### Timepoint

Blood sampling one day before the intervention and 24 hours after the intervention (2 stages)

### Method of measurement

TNF- $\alpha$  kit

## 3

### Description

Serum levels of Clara cell protein (CC16) in male smokers

### Timepoint

Blood sampling one day before the intervention and 24 hours after the intervention (2 stages)

### Method of measurement

CC16 kit

## 4

### Description

Serum levels of surfactant protein-D (SP-D) in male smokers

### Timepoint

Blood sampling one day before the intervention and 24 hours after the intervention (2 stages)

### Method of measurement

SP-D kit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 10 male smokers who did endurance training for 4 weeks (running, 3 days a week with an intensity above 50% of maximum heart rate) and took vitamin D supplement (1000 units per week) with it. In this study, the supplement of the British company Health Aid was used.

#### Category

Other

### 2

#### Description

Intervention group: 10 male smokers who did endurance training for 4 weeks (running, 3 days a week with an intensity above 50% of maximum heart rate).

#### Category

Other

### 3

#### Description

Intervention group: 10 male smokers who took vitamin D supplements (1000 units per week) for 4 weeks. In this study, the supplement of the British company Health Aid was used.

#### Category

Other

### 4

#### Description

Control group: 10 male smokers who did not have endurance training during the intervention (4 weeks) and did not take supplements.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Imam Reza Hospital in Tabriz

#### Full name of responsible person

هومن ناطقیان

#### Street address

Shafa alley, Azadi boulevard

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

0000000000

#### Phone

+98 41 3662 6861

#### Email

hoomannt@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

leila nikniaz

##### Street address

No. Azadi Alvd., Tabriz Town

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

0000000000

##### Phone

+98 41 3662 6861

##### Email

Nikniazleila@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tabriz University of Medical Sciences

#### Proportion provided by this source

50

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Hadi pourmanaf  
**Position**  
Master Educated  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiology  
**Street address**  
No. 497, Banafsheh alley, Valliamr boulevard  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
0000000000  
**Phone**  
+98 914 972 2862  
**Email**  
hadipourmanaf@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Hadi pourmanaf  
**Position**  
master educated  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiology  
**Street address**  
No. 497, Banafsheh alley, Valliamr boulevard  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
0000000000  
**Phone**  
+98 41 3662 6861  
**Email**  
hadipourmanaf@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**

Hadipourmanaf@gmail.com  
**Position**  
master educated  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiology  
**Street address**  
No. 497, Banafsheh alley, Valliamr boulevard  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
0000000000  
**Phone**  
+98 41 3662 6861  
**Email**  
hadipourmanaf@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

En In adress: Sportdezh.rzb.ir

### When the data will become available and for how long

every time

### To whom data/document is available

every one

### Under which criteria data/document could be used

Modeling of the subject, supplementation method and training method is allowed

### From where data/document is obtainable

Send an email to hadipourmanaf@yahoo.com or visit Sportdezh.rzb.ir.

### What processes are involved for a request to access data/document

Send an email to hadipourmanaf@yahoo.com or visit Sportdezh.rzb.ir.

### Comments