

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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- α), 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- α) levels in male smokers

Timepoint

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

Method of measurement

TNF- α 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

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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

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Province

East Azarbaijan

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Phone

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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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person

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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