Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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)

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+98 41 3656 1262

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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 Commitee 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
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

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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Latest degree
Master

Other areas of specialty/work
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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