

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effect of vitamin D supplementation on inflammatory markers, muscle damage indices, performance and body composition in athletes

Protocol summary

Study aim

Effect of vitamin D supplementation on inflammatory markers, muscle damage indices, performance and body composition in athletes

Design

The study has a randomized, double-blind clinical trial design. It has case and control groups with a parallel group design of 100 participants, enrolled between June 2018 and August 2018.

Settings and conduct

The study is conducted at Arsham Health and Fitness Center in Isfahan. Blindness is done both for researchers and for participants. Blinding is conducted by placing the names A and B on the supplements given to the two groups. Until the end of the study and obtaining the results of statistical tests, the identities of the groups are not revealed to the researcher and participant.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participants should exercise 30 minute at least thrice weekly for one year ago exclusion criteria: the existence of diseases; Participants whose smoke: take anti-inflammatory medication (such as aspirin, ibuprofen, acetaminophen); nutritional supplements

Intervention groups

In this study, the intervention group received a vitamin D supplemented per week for 8 weeks, including 50,000 international units of vitamin D3 (Dana pharmaceutical company, Tabriz) The control group also has received placebo in same of shape, color, and size with the vitamin supplement for the 8 weeks

Main outcome variables

Alanine aminotransferase serum level; Aspartate aminotransferase serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171213037856N1**

Registration date: **2018-06-27, 1397/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-27, 1397/04/06**

Update count: **0**

Registration date

2018-06-27, 1397/04/06

Registrant information

Name

Hamid Zolfaghari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 4462

Email address

h.z.7025@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on inflammatory markers, muscle damage indices, performance and body composition in athletes

Public title

effect of vitamin D on athletes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Participants should exercise 30 minute at least thrice weekly for one year ago

Exclusion criteria:

the existence of pathologies diseases Participants whose smoke take anti-inflammatory medication (such as aspirin, ibuprofen and acetaminophen) Consumption nutritional supplements

Age

From **20 years** old to **30 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization will conduct using permuted block random of size 2. Random numbers generated in statistical software and participants divide into the intervention and placebo groups. For this purpose we consider the smaller number as an intervention group and the larger number as the placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, to avoid bias we will use supplements and placebo completely in same of shape, color, and size. Supplements and placebo can be distinguished by the letters of the English alphabet. Participants and researchers will not be aware of these codes until the end of the study. Data collectors and statistical specialist who assess the outcomes divide only two groups with English letters. At the end of the evaluations and conclusions for the final report of the study as an article, the codes of two groups are identified for the researchers by the company producing the supplement and placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Mullasadra Street, Vanak Square, Tehran

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

IR.BMSU.REC.1396.331

Health conditions studied

1

Description of health condition studied

Vitamin D deficiency

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Alanine aminotransferase serum level

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

By enzymatic photometric method (IFCC) with a sensitivity of 2 U / L and a coefficient of variation of 14% will be determined.

2

Description

Aspartate aminotransferase serum level

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

By enzymatic photometric method (IFCC) with a sensitivity of 2 U / L and a coefficient of variation of 14% will be determined.

Secondary outcomes

1

Description

Serum level of vitamin D

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

will be measured by direct competitive immune assay

2

Description

Serum level of lactate dehydrogenase

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

By enzymatic chlorometric method with U / L 5 sensitivity and a change coefficient of 2.1% will be determined.

3

Description

exercise heart rate

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Measurement are taken from the radial artery with forefinger and the middle finger of the right hand placed horizontally

Intervention groups

1

Description

In this study, the intervention group received a vitamin D supplemented per week for 8 weeks, including 50,000 international units of vitamin D3 (Dana pharmaceutical company, Tabriz)

Category

Treatment - Other

2

Description

The control group also has received placebo in same of shape, color, and size with the vitamin supplement for the 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arsham fitness center

Full name of responsible person

Mahmood Tabesh

Street address

Arsham fitness center, Hojjati Street, Najaf Abad,

Isfahan.

City

Isfahan

Province

Isfahan

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8515644574

Phone

+98 31 4272 3369

Email

mahmoudtabesh7@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hosein Rostami

Street address

Baqiyatallah University of Medical Sciences, Mullasadra Street, Vanak Square, Tehran

City

Tehran

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Tehran

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1435916471

Phone

+98 21 8248 3131

Email

hosein_rostami59@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

100

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hamid Zolfaghari

Position

Nutritionist

Latest degree

Master

Other areas of specialty/work

Nutrition

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Baqiyatallah University of Medical Sciences,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hamid Zolfaghari

Position

Nutritionist

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for updating data**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hamid Zolfaghari

Position

Nutritionist

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

Not applicable

Title and more details about the data/document

The data is related to the main outcome of study can be shared

When the data will become available and for how long

Six months after publishing article of study

To whom data/document is available

Researchers at universities

Under which criteria data/document could be used

Only to verify the accuracy of the data and getting to know with the measurement values can be used. All data analysis rights are reserved for the owners of the project to publishing articles.

From where data/document is obtainable

Applicants can email this address H.Z.7025@gmail.com

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

After ensuring the applicant's membership as a faculty member of one of the academic centers, information will be sent to his academic email.

Comments