

# 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

**Postal code**

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

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Tehran

**Postal code**

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**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

**Street address**

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

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**Email**

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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**

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**Phone**

+98 21 8248 3131

**Email**

h.z.7025@gmail.com

**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**