

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of vitamin D supplementation on serum levels of adipose tissue browning endocrine regulators, anabolic hormone and exercise performance in male athletes

#### Protocol summary

##### Study aim

Determining the effects of vitamin D supplementation on serum levels of adipose tissue browning endocrine regulators, anabolic hormone and exercise performance in male athletes

##### Design

This study will be conducted as a randomized, double blind clinical trial with two parallel groups.

##### Settings and conduct

The present study will be conducted on 42 physical education students of Shahid Chamran University, which have regular physical activity.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are as below: Age more than 18 years; Male gender; Intention to participate; BMI between 18.5 to 29.9; Vo2max equal to 40 to 60 ml/kg/min; Regular physical activity for at least three times per week each time Exclusion criteria are as below: No intention to participate; Presence of any metabolic diseases; Presence of diagnosed renal (acute or chronic) and bone disease; Smoking; Using other supplements at the beginning of the study or during past 3 months

##### Intervention groups

Athletes receive the appropriate supplements depending on the intervention or placebo group for 8 weeks. participants in the intervention group receive a vitamin D3 tablet with an 2000 IU dose of Zahrawi Company. Also, people in the placebo group receive a placebo tablet containing maltodextrin that looks like vitamin D supplement.

##### Main outcome variables

Primary outcomes of this study include serum levels of endocrine regulators of white adipose tissue browning (FGF-21, BMP-4, IL-15 and meteorin-like); anabolic hormones (growth hormone, IGF-1, testosterone) and athletic performance (aerobic and anaerobic performance).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131117015424N3**

Registration date: **2018-06-07, 1397/03/17**

Registration timing: **prospective**

Last update: **2018-06-07, 1397/03/17**

Update count: **0**

##### Registration date

2018-06-07, 1397/03/17

##### Registrant information

##### Name

MAjid Mohamadshahi

##### Name of organization / entity

Ahvaz Jundishapur University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 439 2836

##### Email address

mohamadshahi-m@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-01-20, 1397/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effects of vitamin D supplementation on serum levels of adipose tissue browning endocrine regulators, anabolic hormone and exercise performance in male athletes

### Public title

Effects of vitamin D on athletes

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Intention to participate BMI between 18.5 to 29.9  
Vo2max between 40-60 ml/kg/min Regular physical activity for at least three times per week each time

#### Exclusion criteria:

No intention to participate Presence of metabolic diseases Presence of diagnosed renal (acute or chronic) and bone disease Smoking Using other supplements at the beginning of the study or during past 3 months

### Age

From **18 years** old

### Gender

Male

### Phase

3

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **42**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Participants will randomly assigned into two groups receiving either vitamin D supplements or a placebo group, with using random number table.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In the present study, participants and researcher will be blinded to the studying groups. Prior to the study, the cans containing the respective pills will be coded by a person other than the researcher to A and B so that the type of received pills in each group will be blinded for researcher.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz Jondishapour University of Medical Science

##### Street address

Golestan Blvd

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135715794

#### Approval date

2018-04-21, 1397/02/01

#### Ethics committee reference number

IR.AJUMS.REC.1397.012

## Health conditions studied

### 1

#### Description of health condition studied

Athletes

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Serum levels of Fibroblast Growth Factor-21

#### Timepoint

pre-intervention and after 12 weeks of intervention.

#### Method of measurement

Using enzyme-linked immunosorbent assay (ELISA) kit

### 2

#### Description

Serum levels of Bone morphogenetic protein 4

#### Timepoint

pre-intervention and after 12 weeks of intervention.

#### Method of measurement

Using enzyme-linked immunosorbent assay (ELISA) kit

### 3

#### Description

Serum levels of meteorin-like

#### Timepoint

pre-intervention and after 12 weeks of intervention.

#### Method of measurement

Using enzyme-linked immunosorbent assay (ELISA) kit

### 4

#### Description

Serum levels of interleukin-15

#### Timepoint

pre-intervention and after 12 weeks of intervention.

**Method of measurement**

Using enzyme-linked immunosorbent assay (ELISA) kit

**5****Description**

Serum levels of Growth hormone

**Timepoint**

pre-intervention and after 12 weeks of intervention.

**Method of measurement**

Using enzyme-linked immunosorbent assay (ELISA) kit

**6****Description**

Serum levels of Insulin-like growth factor 1

**Timepoint**

pre-intervention and after 12 weeks of intervention.

**Method of measurement**

Using enzyme-linked immunosorbent assay (ELISA) kit

**7****Description**

Serum levels of testosterone

**Timepoint**

pre-intervention and after 12 weeks of intervention.

**Method of measurement**

Using enzyme-linked immunosorbent assay (ELISA) kit

**8****Description**

Aerobic performance

**Timepoint**

pre-intervention and after 12 weeks of intervention.

**Method of measurement**

By estimating the maximal oxygen uptake (Vo<sub>2</sub> max) using the Bruce test

**9****Description**

Anaerobic performance

**Timepoint**

pre-intervention and after 12 weeks of intervention.

**Method of measurement**

Be determined on the basis of 30-second Wingate test using a Monark bike

**Secondary outcomes****1****Description**

Serum levels of cortisol

**Timepoint**

pre-intervention and after 12 weeks of intervention.

**Method of measurement**

Using enzyme-linked immunosorbent assay (ELISA) kit

**2****Description**

Serum levels of Parathyroid hormone

**Timepoint**

pre-intervention and after 12 weeks of intervention.

**Method of measurement**

Using enzyme-linked immunosorbent assay (ELISA) kit

**3****Description**

Serum levels of 25-hydroxy vitamin D

**Timepoint**

pre-intervention and after 12 weeks of intervention.

**Method of measurement**

Using enzyme-linked immunosorbent assay (ELISA) kit

**Intervention groups****1****Description**

Intervention group: Daily intake of vitamin D supplement with a dose of 2000 international unit of Zahrawi company (Iran) for 12 weeks

**Category**

Treatment - Other

**2****Description**

Control group: Daily intake of a placebo that look likes vitamin D supplement and contains maltodextrin

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Faculty of Physical Education, Shahid Chamran University of Ahvaz, Ahvaz, Khuzestan Province

**Full name of responsible person**

Aliakbar Alizadeh

**Street address**

Golestan Blvd

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**Fax****Email**

Oisc@scu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi

**Street address**

Golestan Blvd.

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itc@ajums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Majid Mohamadshahi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ahvaz Jundishapur University of Medical Science,  
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mohamadshahi-m@ajums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Majid Mohamadshahi

**Position**

Associate professor

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Majid Mohamadshahi

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## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

### **Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

### **Informed Consent Form**

No - There is not a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

No - There is not a plan to make this available

### **Data Dictionary**

No - There is not a plan to make this available

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

Data related to outcomes of the study will be published

in the article as a comparison between groups.

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

Data will be available 6 months after publication.

### **To whom data/document is available**

Access to this information will be allowed for researchers and people involved in their work with athletes (such as sports coaches or professional athletes).

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

Data will not be available for analysis to other people, but the study protocol, the method of analysis and the final results will be presented so that people are aware of the correctness of the method of study.

### **From where data/document is obtainable**

You can refer to the Department of Nutrition Faculty of Paramedicine, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, or email shahi334@gmail.com to receive the documentation.

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

If the applicant's request is announced in accordance with the terms, it can be sent to the person within one week.

### **Comments**