Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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
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Province
Khouzestan
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 (Vo2 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
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6135715794
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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