

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Alterations of short-term vitamin D supplementation on the antioxidant capacity and muscle damage indicators responses to exhausting aerobic activity in non-athletic men

Protocol summary

Study aim

The effect of short-term vitamin D supplementation on the antioxidant capacity and muscle damage indicators responses to exhausting aerobic activity in non-athletic men

Design

The present study is a randomized double-blind clinical trial with control group on men overweight.

Settings and conduct

30 samples were divided into experimental group (vitamin D recipient) and placebo (oral paraffin recipient) using a randomized permuted block method. every groups received diet using adjusted ideal body weight. Macronutrient distribution in diet will be given in the form of 65-45% CHO, 10-15% and 30-35% fat. In this study, there are 2 visits for the patient at the beginning, and the end of the study. This study was conducted in the form of double-blind that patients and physicians and investigators be unaware of the type of intervention that they were taking.

Participants/Inclusion and exclusion criteria

Men 20 to 30 years/overweight; no use of any drug and / or surgical treatment; Not having any systemic disease and other endocrine disorders

Intervention groups

In this study, one group receiving vitamin D as intervention group and one group receiving oral paraffin as a control group.

Main outcome variables

Anthropometric indices, liver enzymes, antioxidant capacity, muscle damage, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210414050965N1**

Registration date: **2021-05-04, 1400/02/14**

Registration timing: **prospective**

Last update: **2021-05-04, 1400/02/14**

Update count: **0**

Registration date

2021-05-04, 1400/02/14

Registrant information

Name

Vahid Parvizi

Name of organization / entity

Razi University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-10, 1400/02/20

Expected recruitment end date

2021-06-10, 1400/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Alterations of short-term vitamin D supplementation on the antioxidant capacity and muscle damage indicators

responses to exhausting aerobic activity in non-athletic men

Public title
The effect of short-term vitamin D supplementation on the antioxidant capacity and muscle damage indicators responses to exhausting aerobic activity in non-athletic men

Purpose
Basic science

Inclusion/Exclusion criteria
Inclusion criteria:
Overweight men Age 20 to 30 years Body mass index above 25 to 29.99 Vitamin D deficiency (25 levels of hydroxyvitamin D below 30 nanomoles / liter)
Exclusion criteria:
Muscle injury Uncontrolled intake of vitamin D supplements Doing regular exercise smoking

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

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples were classified using randomized block splitting and divided into two groups using random numbers table. Each participant will have an equal chance of being in each group, and researchers and participants in the study will not be able to predict the type of intervention they receive.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the patients were randomly divided into two groups who were informed about entering the study and were not aware of the type of intervention received. On the other hand, the researcher who does all the information and measurements is also unaware of the type of intervention that each patient receives. A collaborator physician in the study was also blinded to this study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah Razi University

Street address

No.9, Taqh-Bostan Ave, University Blvd, Razi University.

City

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Kermanshah

Postal code

6714967346

Approval date

2021-02-24, 1399/12/06

Ethics committee reference number

IR.RAZI.REC.1400.001

Health conditions studied

1

Description of health condition studied

muscle damage indicators

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Antioxidant capacity

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By blood sampling

2

Description

Muscle damage indicators

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By blood sampling

3

Description

Serum levels of liver enzymes

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Fourteen subjects, Vitamin D supplementation (including receiving vitamin D from Zahravi Pharmaceutical Company, at the rate of 2000 units per day for six weeks), Exhaustive test and negative slope on the treadmill for two sessions (one session before supplementation and one session after supplementation), Control the intensity of exercise using a polar heart rate monitor and the Borg index, Blood sampling in four rounds. The first and second stages of sampling before and after the first training protocol and the third and fourth stages of sampling after the completion of the second training protocol.

Category

Lifestyle

2

Description

Control group: Control group: Fourteen subjects, Receive a placebo containing paraffin made by Zahravi Pharmaceutical Company of Iran (daily for six weeks) which is similar to vitamin D supplement in terms of shape, color, smell and taste. Exhaustive test and negative slope on the treadmill for two sessions (one session before supplementation and one session after supplementation), Control the intensity of exercise using a polar heart rate monitor and the Borg index, Blood sampling in four rounds. The first and second stages of sampling before and after the first training protocol and the third and fourth stages of sampling after the completion of the second training protocol.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam hosein hospital

Full name of responsible person

vahid parvizi mastali

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No.9, Taqh-Bostan Ave, University Blvd, Razi University.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

Full name of responsible person

Rastegar Hoseini

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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

Razi University

Proportion provided by this source

10

Public or private sector

Private

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

Razi Univeristy

Full name of responsible person

Rastegar Hoseini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Nutrition

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data will be record in the SPSS software and will be available.

When the data will become available and for how long

Availability will start nine months after publishing all papers

To whom data/document is available

Only available for researchers in academic and scientific institutions

Under which criteria data/document could be used

All data can be used as reference

From where data/document is obtainable

vahidparvizi1996@gmail.com

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

If the explanation for data request would be convincing it will be given in 3 days.

Comments

not having any