

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of vitamin D in comparison with normal saline on the inflammatory changes and some biochemical factors during a weight training session in bodybuilders

Protocol summary

Summary

The aim of this study is to investigate the effect of vitamin D injection on inflammatory and biochemical changes in vitamin D-deficient athletes during a bodybuilding training session. The study population consists of fourteen athletes presented to nutrition clinic. Athletes are screened based on the inclusion and exclusion criteria. The level of Vitamin D in each participant is measured. Subjects participate in the vitamin D-injected and normal saline-injected protocols with a 4-week period between injections. On the exercise day, fifteen minutes before starting exercise, a catheter is inserted into the peripheral vein and 5 ml blood sample is taken and then separated. Venous bloods are drawn before exercise, immediately after the exercise and one hour after exercise. Serum samples will be stored at -80 °C until assay. The secreted cytokines and hormonal levels are measured using commercially available ELISA kits. Biochemical biomarkers are determined by spectrophotometry method. All measurements will be performed in triplicate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102524699N1**

Registration date: **2016-05-08, 1395/02/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-08, 1395/02/19

Registrant information

Name

Damoon Ashtary-Larky

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 614436106

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Recruitment status

Recruitment complete

Funding source

This project supports by a grant from Ahvaz Jundishapur University of Medical Sciences.

Expected recruitment start date

2015-08-14, 1394/05/23

Expected recruitment end date

2016-01-01, 1394/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D in comparison with normal saline on the inflammatory changes and some biochemical factors during a weight training session in bodybuilders

Public title

The effect of vitamin D on inflammatory changes during exercise

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Male athletes aged 20 to 30 years; training for approximately 2 years; percentage of body

fat in the normal range; without cardiovascular disease and muscular damage Exclusion criteria: weight loss diet over the past month, consumption of any dietary and sport supplements 8 weeks before the study, having acute and chronic illnesses, 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: **14**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

This study is a clinical trial crossover design in which each subject serves as their own control. How to blind? No athlete or examiner knows in what groups the athletes will be placed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz

City

Ahvaz

Postal code

Approval date

2015-08-08, 1394/05/17

Ethics committee reference number

IR.AJUMS.REC.1394.300

Health conditions studied

1

Description of health condition studied

Inflammatory conditions

ICD-10 code

R76.9

ICD-10 code description

Abnormal immunological finding in serum, unspecified

Primary outcomes

1

Description

Tumor necrosis factor alpha

Timepoint

Before workout; immediately after workout; one hour after workout

Method of measurement

ELISA - pg/ml

2

Description

Interleukin 10

Timepoint

Before workout; immediately after workout; one hour after workout

Method of measurement

ELISA - pg/ml

3

Description

Interleukin 6

Timepoint

Before workout; immediately after workout; one hour after workout

Method of measurement

ELISA - pg/ml

4

Description

Insulin

Timepoint

Before workout; immediately after workout; one hour after workout

Method of measurement

ELISA - mcU/ml

5

Description

C-peptide

Timepoint

Before workout; immediately after workout; one hour after workout

Method of measurement

ELISA - ng/ml

6

Description

Vitamin D

Timepoint

Before intervention; before workout

Method of measurement

ELISA - ng/ml

7

Description

Creatine kinase

Timepoint

Before workout; immediately after workout; one hour after workout

Method of measurement

Enzymatic method - U/L

8

Description

Lactate dehydrogenase

Timepoint

Before workout; immediately after workout; one hour after workout

Method of measurement

Enzymatic method - U/L

9

Description

Blood sugar

Timepoint

Before workout; immediately after workout; one hour after workout

Method of measurement

Enzymatic method - mg/dl

10

Description

Percentage body fat

Timepoint

Before workout

Method of measurement

Body fat Analyzer

11

Description

Blood pressure

Timepoint

Before workout; immediately after workout; one hour after workout

Method of measurement

Blood pressure machine

Secondary outcomes

empty

Intervention groups

1

Description

Injection of vitaminD3, 300,000 international units, darou pakhsh, iran, batch No: 932

Category

Treatment - Drugs

2

Description

Injection of normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Otana Health and Fitness Center

Full name of responsible person

Damoon Ashtary-Larky

Street address

Otana Health and Fitness Center, Zeytoon Karmandi, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Fereidoon Najafi

Street address

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz

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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

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Seyyed Ali Mard

Position

Ph.D of physiology

Other areas of specialty/work**Street address**

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Msc. student of clinical biochemistry

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Fax**Email****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty