

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Sep 2026

The effect of 8 weeks interval training with vitamin D supplementation on appetite -depended hormones in overweight men

Protocol summary

Study aim

Evaluation of weight and appetite changes caused by regular exercise and vitamin D supplementation

Design

The present study is a randomized clinical trial and the subjects are assigned in the pretest-posttest design with the control group. Subjects randomly are divided into four groups including: training group with vitamin D supplementation (n=12), training group with placebo(n=12),supplementation group(n=12) and control group(n=12).experimental groups were given 3 sessions per week during 8 weeks .

Settings and conduct

This study is the semi- experimental and double-blind (neither the researcher nor participants are aware of which placebo or supplement group they receive) will be conducted in the Javanroud. The experimental group will perform training in Imam Khomeini cloub and blood sampling from each of the two groups will perform in the Hazrat Rasoul hospital laboratories in Javanrud.

Participants/Inclusion and exclusion criteria

Inclusion criteria:14>Age>30;Over weight (a body mass index above 25kg/m2);Having an informed consent for participation in the study Non-inclusion criteria: Gender(Women); having desaese and taking drugs and supplements; drug and alcohol addiction; having regular exercise in recent 6 months

Intervention groups

Intervention group1: were given 3 sessions per week (85 to 95% max heart rate) during 8 weeks Intervention group2: In addition to given 3 sessions per week (85 to 95% ax heart rate) during 8 weeks,take daily 2000 IU of vitamin D3 supplementation . Intervention group3:Only take daily 2000 IU of vitamin D3 supplementation. Control group:The control will have no supplement and regular exercise program during this time and will only participate in pre-test and post-test measurements.

Main outcome variables

Weight; BMI; appetite related hormones change includes:

Acylated Ghrelin; PYY; Orexin and Insulin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180708040392N2**

Registration date: **2019-09-13, 1398/06/22**

Registration timing: **prospective**

Last update: **2019-09-13, 1398/06/22**

Update count: **0**

Registration date

2019-09-13, 1398/06/22

Registrant information

Name

Naser Rostamzadeh

Name of organization / entity

The University of Kurdistan

Country

Iran (Islamic Republic of)

Phone

+98 87 3371 1530

Email address

n.rostamzadeh@hum.uok.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks interval training with vitamin D supplementation on appetite –depended hormones in overweight men

Public title

The effect of interval training with vitamin D supplementation on appetite –depended hormones

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Being at the age of 14-30 years old BMI>25 kg/m2
Informed consent

Exclusion criteria:

Gender (Women can not be selected as a sample) People who have a certain disease and take medication Having a regular sports activity during recent 6 months Having drug and smoking addiction

Age

From **14 years** old to **30 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by simple drawing method: The researcher devote a number to each of the samples, then they are being selected by using the random number table or the computer model and randomly assigned to one of the groups

Blinding (investigator's opinion)

Double blinded

Blinding description

Both participants and the researcher were kept blind in this study

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University

Street address

Kurdistan University , Pasdaran Blvd.

City

Sanandaj

Province

Kurdistan

Postal code

۶۶۱۷۷-۱۵۱۷۵

Approval date

2019-07-06, 1398/04/15

Ethics committee reference number

IR.UOK.REC.1398.024

Health conditions studied**1****Description of health condition studied**

Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes**1****Description**

Obesity

Timepoint

Before starting the protocol and again after 8 weeks training

Method of measurement

Measure of Body Mass Index (BMI)

2**Description**

Accylated Ghrelin

Timepoint

Before starting the protocol and again after 8 weeks training

Method of measurement

Serum ELISA Kit

3**Description**

PYY

Timepoint

Before starting the protocol and again after 8 weeks training

Method of measurement

Serum ELISA Kit

4

Description

Orexin

Timepoint

Before starting the protocol and again after 8 weeks training

Method of measurement

Serum ELISA Kit

5

Description

Insulin

Timepoint

Before starting the protocol and again after 8 weeks training

Method of measurement

Serum ELISA Kit

Secondary outcomes

1

Description

The amount of calorie intake

Timepoint

before starting the intervention and after a 8 weeks training

Method of measurement

By remember food intake form

Intervention groups

1

Description

Intervention group: do interval training for 8 weeks and taken 2000 IU of vitamin D3 supplement per day

Category

Lifestyle

2

Description

Control group: This group does not receive any intervention and only participates in measurements

Category

Lifestyle

3

Description

Intervention group: do interval training for 8 weeks and taken placebo per day

Category

Placebo

4

Description

Intervention group: taken 2000 IU vitamin D per day

Category

Lifestyle

Recruitment centers

1

Recruitment center**Name of recruitment center**

University of Kurdistan

Full name of responsible person

Naser Rostamzadeh

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No.1, Zibashahr Ave., Baharan Town

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Phone

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Email

n.rostamzadeh@hum.uok.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

The University of Kurdistan

Full name of responsible person

Mehrdad Khamforoush

Street address

University of Kurdistan, Pasdaran, Sanandaj

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m.khamforoush@uok.ac.ir

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

Yes

Title of funding source

The University of Kurdistan

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**

Person responsible for general inquiries

Contact

Name of organization / entity

The University of Kurdistan

Full name of responsible person

Naser Rostamzadeh

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Sport Physiology

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as average age, gender, the average of the body mass index and results of the outcome have the possibility of sharing

When the data will become available and for how long

6 months after the report of results

To whom data/document is available

Researchers in Academic and scientific institutions

Under which criteria data/document could be used

Only for compare with similar research using the documentation permitted

From where data/document is obtainable

By email

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

After sending the request via e-mail, lasts for 2 months

Comments