

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Sep 2026

The effect of aerobic exercise and vitamin C intake on the CK serum level in diabetes type 2

Protocol summary

Study aim

The purpose of this trial was to investigate an aerobic exercise training with vitamin C on serum creatine kinase levels in patients With type 2 diabetes.

Design

The Clinical trial was conducted with 3 intervention groups, the first, the second intervention and the control group. randomized, double blinded accepted.

Settings and conduct

This double-blind study was conducted for 8 weeks at Sistan and Baluchestan University. The intervention groups participated in the exercise training program and used vitamin C supplements. The control group did not receive any activity and did not receive supplementation. Blood samples were prepared before and after the exercise training program, and the serum was separated and frozen at - 26°C until analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Subject should be diabetes type 2 patients. their disease was diagnosed at least one year ago. having ability to stay in the protocol for 2 months. Exclusion criteria: If they take insulin, If they have kidney disease.

Intervention groups

First intervention group: Aerobic training with placebo, exercises for 8 weeks, 3 sessions per week and 45 minutes each session. The main exercises, running with a maximum of 50-60% of maximum heart rate; the placebo was administered at a rate of (250 mg) of starch. Second intervention group: Aerobic exercise plus vitamin C supplementation, in addition to the protocol, 2 hours before the exercise, they took vitamin C , daily (250 mg) of vitamin C, a product of the company (Oswah). Control group that did not participate in any activity and did not take vitamin C supplements.

Main outcome variables

Creatine Kinase Serum Level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041097N1**

Registration date: **2018-11-12, 1397/08/21**

Registration timing: **retrospective**

Last update: **2018-11-12, 1397/08/21**

Update count: **0**

Registration date

2018-11-12, 1397/08/21

Registrant information

Name

Reza Delavar

Name of organization / entity

The University of Sistan and Baluchestan

Country

Iran (Islamic Republic of)

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+98 54 3113 2674

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-29, 1397/02/09

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2018-04-29, 1397/02/09

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

2018-06-22, 1397/04/01

Scientific title

The effect of aerobic exercise and vitamin C intake on the CK serum level in diabetes type 2

Public title

The effect of aerobic exercise and vitamin C intakes on the serum level of creatine kinase in type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients are sure to have type 2 diabetes One year should be passed since their disease diagnosis having Ability to attending the practice protocol for 2 months

Exclusion criteria:

if they take insulin. if they have kidney disease.

Age

From **35 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Vitamin C (supplements) and starches(placebo) were similar in appearance and no apparent differences, any of group didn't have aware of the nature of the pill exercise-complementary and exercise-placebo group.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics Committee of Zahedan University of Medical Sciences

Street address

Medical Sciences Campus, Doctor Hassabi Sqaure

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Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-07-01, 1397/04/10

Ethics committee reference number

IR.ZAUMS.REC.1397.180

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

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

creatine kinase Serum level

Timepoint

Measurement of creatine kinase at the beginning of the study (2 and half hours before the training) and 24 hours after the last exercise session

Method of measurement

kit (CK-NAC)EC2.7.3.2

Secondary outcomes

empty

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

The first intervention group: Aerobic training group with placebo, exercises for 8 weeks, 3 sessions each week and each session for 45 minutes under the supervision of the researcher. The training program included 5 minutes warm-up (soft running, hand and foot comb and gestural movements), 35 minutes of main training included running with a maximum intensity of 50-60% of maximum heart rate and finally 5 minutes of cooling and return to baseline, placebo It was also prescribed (250 mg) of starch each day for two months.

Category

Placebo

2**Description**

Second intervention group: Aerobic exercise group plus vitamin C intake, , consumed vitamin C twice a day for two months each day,2 hours before the exercise, they took vitamin C, 250 mg of vitamin C (a product of the company) (Oswah) And approved by the Ministry of

Health.exercises for 8 weeks, 3 sessions each week and each session for 45 minutes under the supervision of the researcher. The training program included 5 minutes warm-up (soft running, hand and foot comb and gestural movements), 35 minutes of main training included running with a maximum intensity of 50-60% of maximum heart rate and finally 5 minutes of cooling and return to baseline.

Category

Treatment - Drugs

3

Description

Control group: The subjects did not exercise during the 8 weeks of training and did not receive any supplement.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Bou-Ali Hospital

Full name of responsible person

Ms. Fatemeh Pudineh

Street address

Amir Al-Momenin Street, Bu'ali Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University Of Sistan and Baluchestan

Full name of responsible person

Dor Mohammad. Kordi Tamandani. Ph.D

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Central Organization of the University of Sistan and Baluchestan, University Blvd.

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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

The University Of Sistan and Baluchestan

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

The University of Sistan and Baluchestan

Full name of responsible person

Reza Delavar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Related Information to main outcome is possible for sharing

When the data will become available and for how long

Access is available 5 months after the results are printed

To whom data/document is available

Researchers at academia and industry

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Email address

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

There is no specific process

Comments**Person responsible for updating data****Contact****Name of organization / entity**

The University Of Sistan and Baluchestan

Full name of responsible person

Mahla Mahdavi far

Position

Student

Latest degree

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Other areas of specialty/work

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