

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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)

##### Phone

+98 54 3113 2674

##### Email address

delavar@ped.usb.ac.ir

##### 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(pelacebo) 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-pelacebo 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

##### City

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**

Master

**Other areas of specialty/work**

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