Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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 havinig 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 cooing 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 cooing 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

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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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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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Latest degree

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Other areas of specialty/work

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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