Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Effect of Combined Training Course and Aloe Vera supplement on Renal Function and Lipid Profile of Patients with Type 2 Diabetes

Protocol summary

Study aim
The aim of this study was to evaluate the effect of a combined exercise training and aloe vera supplementation on kidney function and lipid profile in patients with type 2 diabetes.

Design
A clinical trial with a control group was performed with two groups of parallel, single blind, simplified random intervention.

Settings and conduct
This study was conducted for 6 weeks in the championship base of the Olympic village of Zahedan city. Participants were blinded by taking placebo.

Participants/Inclusion and exclusion criteria
Entrances criteria: Gender (male); Having type 2 diabetes as diagnosed by a doctor; Age was 40 to 60 years and the ability to attend the exercise protocol for 2 months. Exclusion criteria: Cardiovascular disease, asthma, history of limb fractures, insulin use and diabetes complications including diabetic foot ulcer.

Intervention groups
First intervention group: It was a training group that combined exercises for 6 weeks; 3 sessions per week and each session for 50 to 60 minutes. Combination exercises consisted of 12 repetitions of resistance training for large muscle groups with a intensity of 70% of a maximum repetition; Aerobic exercise includes 10-minute turns with a intensity of 70 to 75% of maximum heart rate on the treadmill. The second intervention group was the training and supplement group, which followed the exercise training protocol as the training group, and in addition, took 500 mg of aloe vera supplement daily for 6 weeks. Control group: They had no exercise or supplementation.

Main outcome variables
The effect of aerobic exercise with and without aloe vera supplementation on renal filtration and possible changes in lipid profile of patients with type 2 diabetes.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180923041097N2**
Registration date: **2020-07-16, 1399/04/26**
Registration timing: **retrospective**

Last update: **2020-07-16, 1399/04/26**
Update count: **0**

Registration date
2020-07-16, 1399/04/26

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2019-11-05, 1398/08/14

Actual recruitment start date
2019-10-20, 1398/07/28

Actual recruitment end date
2019-12-06, 1398/09/15

Trial completion date
2020-01-30, 1398/11/10

Scientific title
Effect of Combined Training Course and Aloe Vera supplement on Renal Function and Lipid Profile of Patients with Type 2 Diabetes

Public title
Effect of Combined Training Course and Aloe Vera supplement on Renal Function and Lipid Profile of Patients with Type 2 Diabetes

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Criteria for inclusion in the study: - male gender. - Having type 2 diabetes as diagnosed by a doctor. - Age 40 to 60 years old. - Physical strength required to attend a exercise protocol for 2 months.

Exclusion criteria:
Criteria for non-inclusion in the study were: - cardiovascular disease. - Asthma. - having a history of broken limbs. - The use of insulin. - complications of diabetes, including diabetic foot ulcers.

Age
From **40 years** old to **60 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **36**
Actual sample size reached: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation method was performed in the form of blocks with predetermined sizes so that the subjects were divided into equal numbers in the research groups in such a way that each subject was assigned a code and then based on a lottery were placed in research groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
One of the Experimental groups of the study was the Exercise+Supplement group, which received the supplement in the form of a capsule along with the Exercise, and the second Experimental group was the Exercise group, which only exercised, and a capsule that looks like a supplement but contains It was Starch, it received.

Placebo
Used

Assignment
Parallel

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
Daneshgah Street, University of Sistan and Baluchestan

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Approval date
2019-03-10, 1397/12/19

Ethics committee reference number
IR.ZAUMS.REC.1397.512

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11.2

ICD-10 code description
Type 2 diabetes mellitus with kidney complications

Primary outcomes

1

Description
Blood creatinine, The normal level of creatinine is 0.8 to 1.4 mg/dL. Females usually have a lower creatinine (0.6 to 1.2 mg/dL) than males, because they usually have less muscle mass. Creatinine is a by-product of normal muscle breakdown. Measuring the levels of creatinine in the bloodstream and in the urine can be helpful for tracking the progression of diabetic kidney disease.

Timepoint
Primary blood sampling was performed 24 hours before the start of exercise training protocol and final stage blood sampling was performed 48 hours after the last exercise training session.

Method of measurement
To measure serum creatinine, a technical creatinine assay kit made by Pars Azmoun Company, Iran, was used.

2

Description
Diabetes is associated with quantitative changes in the amount of circulating lipids – notably an reduction in HDL. Like other lipoproteins, HDL also undergoes significant qualitative changes in diabetes, in both

structure and function.

Timepoint

Measurement of serum lipoprotein HDL was performed in two stages, the first stage in the initial blood sampling, ie 24 hours before the start of exercise training protocol and the second stage in the final stage blood sampling, ie 48 hours after the last exercise session.

Method of measurement

To measure the concentration of HDL index (mg / dL), deposition method with bridging anions and divalent cations was used.

3

Description

LDL cholesterol levels in people with diabetes are not higher than those in people without diabetes who are matched for age, sex, and body weight. In fact, the most common LDL cholesterol level in diabetes is “borderline high” (130-159 mg/dl).

Timepoint

Measurement of serum lipoprotein LDL was performed in two stages, the first stage in the initial blood sampling, ie 24 hours before the start of exercise training protocol and the second stage in the final stage blood sampling, ie 48 hours after the last exercise session.

Method of measurement

The Friedwall equation was used to measure the concentration of LDL (mg / dL).

4

Description

Lipid abnormalities in patients with diabetes,that termed “diabetic dyslipidemia”, are typically characterized by high triglyceride (Tg).

Timepoint

Measurement of serum TG was performed in two stages, the first stage in the initial blood sampling, ie 24 hours before the start of exercise training protocol and the second stage in the final stage blood sampling, ie 48 hours after the last exercise session.

Method of measurement

Triglyceride index concentration (mg / dL) was measured enzymatically using a technical triglyceride assay kit made by Pars Azmoun and AutoAnalyzer (1000RA).

Secondary outcomes

1

Description

Determines of kidney disease level based on the presence of kidney damage and glomerular filtration rate (GFR), which is a measure of level of kidney function, as chronic kidney disease progresses, GFR number decreases.

Timepoint

The calculation of glomerular filtration of the subjects was done in two stages, the first stage in the initial blood sampling, ie 24 hours before the start of exercise training protocol and the second stage in the final stage blood sampling, ie 48 hours after the last exercise session.

Method of measurement

Glomerular filtration rate (GFR) was also calculated from the following formula. eGFR = [186 × (serum creatinine / 88.4) - 1.154] × (age) - 0.203 × (0.742).

Intervention groups

1

Description

Control group: The subjects in this group did not do any exercise during the research period (6 weeks) and did not receive any supplements.

Category

Other

2

Description

The second intervention group was the exercise group that during the research period (6 weeks, 3 days per week and 50-60 minutes every day), only did exercise. Combined exercise includes resistance exercises (2 turns of 12 repetitions of special resistance exercises for large muscle groups with an intensity of 70% of 1RM. Rest time between turns was 2 minutes) and aerobic exercise (2 turns of 10-minute runs with 70-75% of maximum heart rate on a treadmill). A polar heart rate monitor was used to control the desired heart rate. It is noteworthy that the exercises training took place from 5 to 6 p.m. Subjects performed static stretching and flexion movements before and after each training session to warm and cool the body.

Category

Other

3

Description

Third intervention group: Exercise + supplement group. Subjects in this group performed combined exercises with the exercise group and, in addition, received 500 mg/day of aloe vera supplement (manufactured by Supernatural Canada) for 6 weeks during the study period.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Bu Ali Hospital, Zahedan

Full name of responsible person

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Sponsors / Funding sources

1

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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
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
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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
Information about the main outcome can be shared.
When the data will become available and for how long
Possibility to access 05 months after printing the results.
To whom data/document is available
Researchers in academic institutions and industry
Under which criteria data/document could be used
No special conditions are considered
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