

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of 8 weeks of aerobic exercise and astaxanthin supplementation on humanin protein expression, miR-17, miR-146a and miR-155, and inflammatory conditions, oxidative stress and apoptosis in women with type 2 diabetes

Protocol summary

Study aim

Investigating the effect of 8 weeks of combined training with astaxanthin supplementation on the expression of HN protein, miR-17, miR-155, miR-146a, inflammation, oxidative stress and apoptosis in type 2 diabetic patients.

Design

Clinical trial with control group, with parallel groups, single-blind, randomized

Settings and conduct

The exercises are done for 8 weeks (3 sessions per week). Training groups get to know the environment and exercises before starting sports programs. Also, the consent form for participating in the research will be obtained from all the participants.

Participants/Inclusion and exclusion criteria

Patients will be excluded from the study if they have any of the following conditions: a history of ketoacidosis within 6 months before enrollment in the study, excessive hyperglycemia (HbA1c > 10%), diabetic microvascular complications, diabetic neuropathy, impaired liver function (plasma aminotransferase and/or γ -glutamyltransferase levels above the upper limit of normal for age and sex), impaired renal function (serum creatinine levels above the normal range for age and sex), severe anemia, uncontrolled hypertension (hypertension > 100/170 mmHg). Patients with cardiovascular disease (class I-IV congestive heart failure or history of myocardial infarction), obvious heart-related symptoms or history of cerebrovascular events will also be excluded. Active patients who reported more than 1 exercise per week and patients on insulin therapy will not be eligible.

Intervention groups

Five groups of aerobic exercise (15 people), aerobic exercise with placebo (15 people), aerobic exercise with

astaxanthin supplement (15 people), astaxanthin supplement use (15 people) and control group with placebo (15 people) were divided.

Main outcome variables

Humanin serum levels; antioxidant capacity; serum levels of antioxidant enzymes; TNF- α ; IL-10; BAX; BCL2 : miR-17: miR-146: miR-155

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230225057524N1**

Registration date: **2023-03-20, 1401/12/29**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-20, 1401/12/29**

Update count: **0**

Registration date

2023-03-20, 1401/12/29

Registrant information

Name

keyvan Khoramipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-24, 1401/12/05

Expected recruitment end date

2023-04-25, 1402/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks of aerobic exercise and astaxanthin supplementation on humanin protein expression, miR-17, miR-146a and miR-155, and inflammatory conditions, oxidative stress and apoptosis in women with type 2 diabetes

Public title

Effect of aerobic exercise and astaxanthin supplementation on humanin protein expression

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Minimum age 30 and maximum 55 years Excessive hyperglycemia (HbA1c > 10%) Diabetic microvascular complications Diabetic neuropathy Impaired liver function (plasma aminotransferase and/or g-glutamyltransferase level above the upper limit of normal for age and sex) Renal dysfunction (serum creatinine level higher than normal for age and sex) Severe anemia Uncontrolled blood pressure (blood pressure > 100/170 mm Hg) Obvious heart-related symptoms or history of cerebrovascular events Patients with cardiovascular disease (class I-IV congestive heart failure or history of myocardial infarction) Patients on insulin therapy will not be eligible Active patients who reported more than 1 exercise per week

Exclusion criteria:

Patients treated with insulin Having no history of cardiovascular diseases and respiratory problems Patients who do sports.

Age

From **30 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method; The law of random assignment is the simplest method of limited randomization. This method represents a large block for the entire sample size, which means that the balance in

the number of people assigned to each group will be achieved at the end of the study. For this purpose, the researcher first determined a total sample size, then randomly assigned groups of them to group A and the rest to group B. For example, in a study with a sample size of 200 people, 100 balls for intervention groups A and 100. The ball for intervention group B is placed in a lottery container, and then the balls are randomly removed from the container without replacement, and the created sequence is recorded.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants in the design and the person who performs the data analysis are unaware of the study group assignment (which group received the supplement and which group received the placebo).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Kerman Medical Sciences

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kerman, Pajohesh Square

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-02-05, 1401/11/16

Ethics committee reference number

IR.KMU.REC.1401.530

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

diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Percentage of women with type 2 diabetes

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

Blood sugar test

Secondary outcomes

1

Description

Humanin serum levels

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

HN concentration will be measured by an ELISA kit [Human Peptide ELISA Kit (MT-RNR2), Baltimore, MD] with an analytical sensitivity of 7 pg/ml and a detection range of 1800-28 pg/ml.

2

Description

TNF- α serum levels

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

TNF- α levels will be evaluated using enzyme-linked immunosorbent assay (ELISA) following the instructions of commercial kits. The results will be presented as pg/mg of protein.

3

Description

IL-6 serum levels

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

IL-6 levels will be assessed using enzyme-linked immunosorbent assay (ELISA) following the instructions of commercial kits. The results will be presented as pg/mg of protein.

4

Description

Quantification of miR-146a

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

RT-qPCR method is used to investigate the values of miR-146a .

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Description

Quantification of miR-26a

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

RT-qPCR method is used to investigate the values of miR-26a .

6

Description

Measurement of insulin serum levels

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

Serum insulin levels will be measured by ELISA using the Mercodia Insulin Rat ELISA kit (made in Sweden) with a coefficient of variation of 2.6 and a sensitivity of 0.07 microunits per deciliter.

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Description

IR-HOMA and HOMA-B index

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

It will be evaluated using the following formula HOMA-IR = (glucose in mmol/L x insulin in mIU/mL)/22.5 HOMA-B = (20 x insulin in mIU/mL)/(glucose in mmol/L - 3.5)

8

Description

Insulin sensitivity

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

QUICKI تعیین شده بر اساس معادله QUICKI با استفاده از شاخص $QUICKI = 1 / (\log \text{insulin [AIU/mL]} + \log \text{glucose [mg/dL]})$ خواهد ارزیابی شود. شاخص پایین نشان دهنده حساسیت کم به انسولین QUICKI شد. شاخص بالا نشان دهنده حساسیت به QUICKI است، در حالی که شاخص انسولین بالا است.

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Description

Determination of serum glucose concentration

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

Fasting glucose concentration will be measured using Iran's Pars test kit and calorimeter (glucose oxidase) method.

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Description

Determination of BAX and BCL2 serum levels

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

To investigate the concentration of Bax and Bcl2, it will be done using the ELISA kit of Podgin Teb Company

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Description

measurement of superoxide dismutase (SOD)

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

The amount of superoxide dismutase activity is indirectly measured using the calorimetric method based on the ability of SOD to inhibit pyrogallol autoxidation.

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Description

Measurement of Glutathione Peroxidase (GPX)

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

Glutathione peroxidase assay is based on the ability of glutathione peroxidase to oxidize glutathione (GSH) to oxidized glutathione (GSSH). (GSSH) is part of the reactions that reduce cumene hydroperoxide.

Glutathione reductase then converts GSSH to GSH by consuming nicotinamide dinucleotide phosphate (NADPH). The reduction of NADPH measured at 340 nm is an indicator of glutathione peroxidase activity.

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Description

Determination of malondialdehyde (MDA)

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

It will be determined based on the reaction with thiobarbituric acid (TBA) and using a spectrophotometric method at a wavelength of 532 nm.

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Description

Measurement of total antioxidant capacity

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

Antioxidant capacity is measured by LDN Germany Company kit.

Intervention groups

1

Description

Intervention group 1: will receive only the interventions of 8 weeks of aerobic training (weeks one to four will be 3 sessions and weeks four to eight will be 4 sessions per week).

Category

Treatment - Other

2

Description

Intervention group 2: This group will receive the interventions of 8 weeks of aerobic exercise (weeks one to four will be 3 sessions and weeks four to eight will be 4 sessions per week) along with 12 mg of the base substance alone as a placebo. These ingredients will be consumed with lunch for 8 weeks.

Category

Treatment - Other

3

Description

Intervention group 3: This intervention group will receive 8 weeks of aerobic training (weeks one to four will be 3 sessions and weeks four to eight will be 4 sessions per week) along with subjects taking 12 mg of astaxanthin supplement daily. The content of the supplement will be astaxanthin from hematochus algae (made in the USA). These ingredients will be consumed with lunch for 8 weeks.

Category

Treatment - Other

4

Description

Intervention group 4: This intervention group will only receive 12 mg of astaxanthin supplement daily. The content of the supplement will be astaxanthin from hematochus algae (made in the USA). These ingredients will be consumed with lunch for 8 weeks.

Category

Treatment - Other

5

Description

Control group: This intervention group will only receive 12 milligrams of the basic substance as a placebo daily. These ingredients will be consumed with lunch for 8 weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Laboratories in Kerman city

Full name of responsible person

Keyvan Khorampour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr. Reza Malekpour Afshar

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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

Kerman University of Medical Sciences

Proportion provided by this source
20

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
Kerman University of Medical Sciences

Full name of responsible person
Keyvan Khoramipour

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
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

All data is potentially shareable after de-identifying

individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

داده های شما فقط برای محققین شاغل در موسسات دانشگاهی و علمی در دسترس خواهد بود

Under which criteria data/document could be used

Use in meta-analysis articles

From where data/document is obtainable

To receive the desired documents or data, refer to the email of Dr. Keyvan Khorramipour.

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

Six months after the time of publication of the results in a valid journal, in case of additional research work

Comments