Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 scienece
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
Street address
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 .

5

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.

7

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

9

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.

10

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

11

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.

12

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.

14

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 Khorampiour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Keyvan Khoramipour
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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