Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of aerobic training and spirulina supplementation on resistin and CRP in women with type 2 diabetes

Protocol summary

Study aim
evaluate the effect of aerobic training with Spirulina supplementation on resistin and CRP in women with type 2 diabetes

Design
Exercise and Supplement, Exercise, Supplement, control a clinical trial with a control group, with parallel groups, randomized. The sample size is 10 people in each group.

Settings and conduct
The statistical population of this study is women with type 2 diabetes mellitus in Qom city. 60 of these people are selected based on inclusion and exclusion criteria the research. After completion of the consent form, the anthropometric and blood glucose characteristics of the subjects were recorded and based on the blood glucose of the subjects, the subjects were divided into four groups: 1_ aerobic + spirulina (15), 2_ aerobic (15 subjects), 3_ supplements (15 people), 4_ controls (15 people). Blood sampling is performed in two steps, one day before the training sessions and 48 hours after the end of the training. Spirulina supplementation is 2 grams per day for supplemental groups. Research variables will be measured after 6 weeks of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: No Appearance and clinical signs of cardiovascular disease

Intervention groups
1. Aerobic group : Three sessions per week for 6 weeks
2. Spirulina supplements: Take 2 grams of spirulina daily
3. Supplement and Exercise Group: Two grams of spirulina supplement per day and three sessions of exercise per week for 6 weeks 3. Control group: no exercise and supplement

Main outcome variables
serum levels of resistin and CRP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171008036653N2**
Registration date: **2020-01-03, 1398/10/13**
Registration timing: **retrospective**

Last update: **2020-01-03, 1398/10/13**
Update count: **0**

Registration date
2020-01-03, 1398/10/13

Registrant information

Name
mohsen akbarpour

Name of organization / entity
university of qom

Country
Iran (Islamic Republic of)

Phone
+98 25 3210 3690

Email address
m.akbarpoor@qom.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
2019-11-22, 1398/09/01

Actual recruitment end date
2019-12-22, 1398/10/01

Trial completion date
2020-01-21, 1398/11/01

Scientific title
The effect of aerobic training and spirulina supplementation on resistin and CRP in women with type

2 diabetes

Public title
The effect of exercise training and spirulina supplementation on type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No clinical signs of cardiovascular disease T2D detection < 10 years ago Ages 40 to 50years old No dependency to insulin The use of commonly used diabetes medications, such as metformin and glenalbelamine
Exclusion criteria:
Cardiovascular disease Coronary artery disease Atrial fibrillation High blood pressure Congenital heart disease Retinopathy Neuropathy Body mass index 25-30 Ischemia in echocardiography Disability that causes difficulty in practice
Age
From **40 years** old to **50 years** old
Gender
Female

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, a simple randomization method will be used. The participants will be divided into 4 groups of 15 people. For this purpose, It is written from 1 to 4 numbers, (There are 15 Repeat from each number) on the paper. Participants are asked that Each person take a number. so They will be grouped based on the number they picked.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Qom
Street address
street alghadir,University of Qom
City
Qom
Province
Ghoum
Postal code
3716146611
Approval date
2019-08-31, 1398/06/09
Ethics committee reference number
IR.QOM.REC.1398.007

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
Serum Resistin in women with type 2 diabetes
Timepoint
One day before the session begins and 48 hours after the end of the exercise
Method of measurement
The serum level of resistin will be measured by ELISA and using a commercial kit under the manufacturer's protocols (ZellBio GmbH, Germany).

2

Description
Serum CRP in women with type 2 diabetes
Timepoint
One day before the session begins and 48 hours after the end of the exercise
Method of measurement
The serum level of CRP will be measured by ELISA and using a commercial kit under the manufacturer's protocols .

Secondary outcomes

empty

Intervention groups

1

Description
first Intervention group: The training group consisted of three sessions per week of aerobic training for 6 weeks. Training sessions consisted of 45 minutes walk or running on a treadmill. Each session is divided into 10 minutes of warming up , 10 minutes of cooling down with

and 25 minutes of aerobic training (with an intensity of 65to 75% HRR).

Category

Other

2

Description

Group 2: Spirulina 2 grams daily, including 4 pills 500 mg before meals, for 6 weeks. This supplement is made by Qeshm algae and contains spirulina pure green algae. spirulina is a blue-green wonder aglae.

Category

Other

3

Description

Third intervention group: Exercise + supplement group consisting of three sessions per week of aerobic training for 6weeks and 2 grams of supplementation of spirulina per day for 6 weeks

Category

Other

4

Description

fourth intervention group: control group, No Spirulina supplement and no exercise

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom Diabetes Association

Full name of responsible person

Qom Diabetes Association

Street address

Street Enghelab

City

Qom

Province

Ghoum

Postal code

371586791

Phone

+98 25 3210 3667

Email

ss.kk1159@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Qom

Full name of responsible person

Yaghob Norozi

Street address

Street Alghadir,University of Qom

City

Qom

Province

Ghoum

Postal code

3716146611

Phone

+98 25 3210 3690

Email

f.fathollahi1363@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The University of Qom

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 Qom

Full name of responsible person

Mohsen Akbarpour

Position

Association Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

Street address

Street Alghadir,University of Qom

City

Qom

Province

Ghoum

Postal code

3716146611

Phone

+98 25 3210 3667

Email

akbarpour.mohsen@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
The University of Qom

Full name of responsible person
Mohsen Akbarpour

Position
Association Professor

Latest degree
Ph.D.

Other areas of specialty/work
Others

Street address
Street Alghadir,University of Qom

City
Qom

Province
Ghoum

Postal code
3716146611

Phone
+98 25 3210 3667

Email
akbarpour.mohsen@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
The University of Qom

Full name of responsible person
Mohsen Akbarpour

Position
Association Professor

Latest degree
Ph.D.

Other areas of specialty/work
Others

Street address
Street Alghadir,University of Qom

City
Qom

Province
Ghoum

Postal code
3716146611

Phone
+98 25 3210 3667

Email
akbarpour.mohsen@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information.

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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The informed consent form will be available to others without mentioning the names of the participants. Details of the study process are also provided in detail in the file format.

When the data will become available and for how long
Start of the 6 month period after the research

To whom data/document is available
For university students and students in research related fields

Under which criteria data/document could be used
There are no specific conditions to provide such information.

From where data/document is obtainable
Mohsen akbarpour

What processes are involved for a request to access data/document
Send message to the person responsible for providing the data

Comments