Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of aerobic training with silymarin consumption on some cardiovascular risk factors in men with type 2 diabetes

Protocol summary

Study aim
The effect of aerobic training with silymarin consumption on some cardiovascular risk factors in men with type 2 diabetes

Design
The study population consists of all male diabetic patients in Gachsaran city with 3 years of diabetes history who participate in the research voluntarily and are randomly divided into 4 research groups based on weight.

Settings and conduct
At first, by announcing a call in the diabetic patients' associations and other places of Gachsaran city, all types of diabetic patients were invited in an announcement. Then, in a briefing session, the potential risks and benefits of participating in the present study were explained to all participants. to make them unable to do physical activity were selected.all subjects competed the consent form.Subjects were randomly divided into 4 groups, including: (1) control plus placebo (coated tablet containing wheat flour), (2) aerobic training , (3) aerobic training plus silymarin supplementation, and (4) silymarin consumption.Silymarin receiving groups consumed coated tablets containing 140 mg / kg silymarin daily (one after breakfast and one after dinner) by the Livergol brand manufactured by GolDarou Company

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diabetic history 3 years and more, age 40 to 50 years; Exclusion criteria: high blood pressure, smoking, regular exercise in the last 2 years

Intervention groups
The control group has no exercise activity for 2 months and also does not take silymarin. The aerobic training group (2) trained for eight weeks, three sessions per week and each session for 20-45 minutes at an intensity of 60 to 85% of the reserved heart rate. Both silymarin groups (3) take two 140 mg coated silymarin tablets daily. Aerobic training group plus silymarin (4) exercise for 2 months and use silymarin tablets.

Main outcome variables
Triglyceride; Cholesterol

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200215046506N3**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **retrospective**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

Registration date
2020-06-02, 1399/03/13

Registrant information

Name
Ali Khajehlandi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 74 3233 5910

Email address
a.khajehlandi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-10, 1398/10/20

Expected recruitment end date
2020-03-10, 1398/12/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aerobic training with silymarin consumption on some cardiovascular risk factors in men with type 2 diabetes

Public title

The effect of aerobic training with silymarin consumption on some cardiovascular risk factors in men with type 2 diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients who have had a minimum of 3 years of diabetes Age of participants 40 - 50 years

Exclusion criteria:

The lack having the effects of diabetes, like diabetic foot ulcers The lack history of heart disease and lung disease The lack regular exercise of athletic activity in the last two years The lack of tobacco in the last six months

Age

From **40 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was carried out based on permuted block randomization, using random allocation software. Considering 60 subjects in the sample and 4 treatment period, 15 four-odd blocks for randomization are considered.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University ,Gachsaran Branch

Street address

Daneshjo Blvd.,Gachsaran

City

Gachsaran

Province

Kohgilouyeh-va-Boyrahmad

Postal code

63876-75818

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

IR.IAU.IAUG.REC.1398.005

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Triglyceride

Timepoint

Two months after intervention

Method of measurement

Blood serum

Secondary outcomes

1

Description

Weight Lose

Timepoint

Two months after training

Method of measurement

By Scale

Intervention groups

1

Description

Intervention group: Three sessions of exercise per week and each session 20-45 minutes with intensity of 60 to 85% of heart rate reserve, for eight weeks

Category

Other

2

Description

Intervention group: Use silymarin for 8 weeks daily in two coats of 140 mg silicarin coated tablets (one after breakfast and one after dinner) with the Lever Flower brand manufactured by Gul Daroo Company (economic code IRC12280250372).

Category
Other

3

Description
Intervention group: Three sessions of exercise per week, each session of 20-45 minutes, with 60-85% heart rate reserve plus silymarin for 8 weeks daily, two 140 mg silicarin-coated tablets (one after breakfast and one with breakfast). After Dinner) By Liver Flower brand made by Gol Daroo Company (economic code IRC12280250372)

Category
Other

4

Description
Control group: Take a coated tablet containing wheat flour

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University, Gachcaran Branch

Full name of responsible person
ALI Khajehlandi

Street address
No.12, North Tenth Ave., Valiasr Blvd., Gachsaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research, Islamic Azad University Gachsaran Branch

Full name of responsible person
Amin Mohammadi

Street address
No.31,Western Eighth Ave., shahed Blvd.,Razmandegan Town

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Email
Amin.mohammadi8@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for research, Islamic Azad University Gachsaran Branch

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University Gachsaran Branch

Full name of responsible person
Ali Khajehlandi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physical Education and Sport Sciences

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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