

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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 completed 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-Boyerahmad

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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Province

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7581796481

Phone

+98 74 3233 5333

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

Contact

Name of organization / entity
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Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Position
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Latest degree

Ph.D.

Other areas of specialty/work
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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