

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of eight weeks of aerobic training with silymarin consumption on glycemic indices and liver enzymes in men with type 2 diabetes

Protocol summary

Study aim

Aim of research: review the effect of eight weeks of aerobic training with silymarin consumption on glycemic indices and liver enzymes in men with type 2 diabetes

Design

Study population of all male diabetic patients in Gachsaran city with 3 years history of diabetes who volunteered to participate in the study and randomly divided into 4 groups.

Settings and conduct

Initially, a notice was issued to notify all diabetic patients associations; announcements were issued to notify all patients with type 2 diabetes all over Gachsaran city. Then, in a briefing session, the potential risks and benefits of participating in the present study were explained to all participants. Those unable to do physical activity were selected. All subjects completed the consent form. Subjects were randomly divided into 4 groups, including: (1) control + placebo (2) aerobic training + placebo (coated tablet containing wheat flour) (3) aerobic training + 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 (economic code IRC12280250372)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic history of 3 years or more. Age 40 to 50 years. Exclusion criteria: Special diseases like hypertension; Smoking; Regular exercises in two last years

Intervention groups

The control group (1) did not exercise for 2 months and did not take silymarin. The aerobic training group (2) trained for eight weeks, three sessions per week and each session for 20-45 minutes with an intensity of 60 to 85% of the stored heart rate. The silymarin group (3) consumes two 140 mg silicone-coated tablets

daily. Aerobic Exercise + Silymarin (4) group exercise for 2 months and use Silymarin tablets.

Main outcome variables

Glucose; insulin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200215046506N1**

Registration date: **2020-02-27, 1398/12/08**

Registration timing: **retrospective**

Last update: **2020-02-27, 1398/12/08**

Update count: **0**

Registration date

2020-02-27, 1398/12/08

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

2019-07-23, 1398/05/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of aerobic training with silymarin consumption on glycemic indices and liver enzymes in men with type 2 diabetes

Public title

The effect of eight weeks of aerobic training with silymarin consumption on glycemic indices and liver enzymes 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

AgeFrom **40 years** old to **50 years** old**Gender**

Male

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

In order to randomly assign the samples to four groups, Excel software is used as follows: First, a list of participants is compiled and we assign each participant a specific number using the RAW function, then randomly select each participant using the RANDBETWEEN and VLOOKUP functions and assign them to each participant. We assign 4 groups to groups. The first, second, third and fourth subjects were assigned to the control group, aerobic exercise group, silymarin supplementation group, and aerobic training + silymarin group, respectively. Others are assigned to groups in the same way.

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-Boyrabad

Postal code

63876-75818

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

IR.IAU.IAUG.REC.1398.006

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**

Glucose

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, Gacharan Branch

Full name of responsible person
ALI Khajehlandi

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

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Email
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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
Ali Khajehlandi

Street address
No.12, North Tenth Ave., Valiasr Blvd., Karconan Town

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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
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

Ali Khajehlandi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physical Education

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Person responsible for updating data

Contact

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Full name of responsible person

Ali Khajehlandi

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Others

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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