Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

T 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. 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 + 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
Age
From **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-Boyrahmad
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, 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

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
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physical Education

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Person responsible for updating data

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Faculty Member

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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