

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of eight weeks of combined exercises and consumption of grape seed extract on some parameters of oxidative and antioxidant stress, total antioxidant capacity (tac), malondialdehyde (mda) and reduced glutathione (gsh) in women with diabetes

Protocol summary

Study aim

Determining the effect of eight weeks of combined exercises and consumption of grape seed extract on some parameters of oxidative and antioxidant stress, total antioxidant capacity (tac), malondialdehyde (mda) and reduced glutathione (gsh) in women with diabetes

Design

Clinical trial with control group, with parallel groups, randomized, on 60 patients. Randomization by the method of equal blocks (15 blocks of 4) in which a number of intervention people and a number of comparison people are included in each block.

Settings and conduct

By referring to Hamedan Ba'ath Hospital, eligible people were identified and placed in the intervention groups using equal blocks randomization (15 blocks of 4). Then, people will go to the sports club for training intervention and perform exercises and supplements for 8 weeks. And before and 24 hours after exercise interventions, blood samples are taken from people to be measured in the laboratory.

Participants/Inclusion and exclusion criteria

Entry requirements: suffering from diabetes, being menopausal, Age range 50-65 years Conditions of non-entry: inability to practice, History of cardiovascular disease

Intervention groups

Exercises and supplements group: In the exercises group, the samples are subjected to combined exercises and the supplement group consumes grape seed extract. The control group is not subjected to any intervention.

Main outcome variables

diabetes, some antioxidant factors (total antioxidant capacity and malondialdehyde and reduced glutathione)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056548N9**

Registration date: **2023-07-10, 1402/04/19**

Registration timing: **prospective**

Last update: **2023-07-10, 1402/04/19**

Update count: **0**

Registration date

2023-07-10, 1402/04/19

Registrant information

Name

Saeid Shamlou kazemi

Name of organization / entity

Bu-Ali Sina university

Country

Iran (Islamic Republic of)

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+98 912 859 7297

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-12, 1402/04/21

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of eight weeks of combined exercises and consumption of grape seed extract on some parameters of oxidative and antioxidant stress, total antioxidant capacity (tac), malondialdehyde (mda) and reduced glutathione (gsh) in women with diabetes

Public title

The effect of exercise and consumption of grape seed extract on diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having diabetes being menopausal Age range 50-65 years

Exclusion criteria:

History of cardiovascular disease Inability to exercise

Age

From **50 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this randomization, the method of equal blocks (15 blocks of 4) has been used, in which a number of intervention people and a number of comparison people are included in each block, and we have allocated them to different groups. The method and tool of block random sequence generation has been done using <https://www.sealedenvelope.com/simple-randomiser/v1/lists>.

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 Sport Sciences Research

Institute

Street address

Fifth Alley, Mir Emad Ave., Ostad Motahari Ave

City

Tehran

Province

Tehran

Postal code

1474674646

Approval date

2023-06-21, 1402/03/31

Ethics committee reference number

IR.SSRC.REC.1402.061

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

The percentage of people whose blood sugar levels have decreased.

Timepoint

Before and after interventions

Method of measurement

By measuring blood sugar in the laboratory

Secondary outcomes

1

Description

The percentage of people in whom the level of total antioxidant capacity and reduced glutathione increased and malondialdehyde decreased.

Timepoint

Before and after interventions

Method of measurement

Using ELISA method and Zell bio kit made in Germany

Intervention groups

1

Description

Intervention group: Sports intervention includes 8 weeks of combined exercises (selected aerobic and resistance exercises). According to the instructions of the American College of Sports Medicine (ACSM), the participants start training three times a week for fifty minutes, and the intensity and duration of the training is increased during

8 weeks. All exercises are performed under the supervision of a sports physiology specialist and in the health sports clinic. For aerobic exercise, participants choose to exercise on a treadmill or bicycle ergometer. Aerobic training sessions start from 20 minutes and with an intensity of 60% of the maximum heart rate in the first and second week and increase to 30 minutes and up to 70% of the maximum heart rate in the 8th week. During the training, the heart rate is monitored by a Polar T31 oy pacemaker. Resistance training begins with one set of 15 repetitions for each movement in the first two weeks, and finally the intensity of the training is increased to two or three sets of 10-120 repetitions. It increases in week 8. All resistance exercises are performed by means of gym machines and include chest press, leg press, cable underarm, cable front arm and cable back arm. The supplement group of grape seed extract is also consumed in the form of 200 mg capsules of grape seed extract of Vinicin Barrage essence for eight weeks and every day.

Category

Treatment - Other

2

Description

Control group: This group is not subject to any exercise intervention or supplement consumption.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Saeid Shamlou Kazemi

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6517838695

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saeidshamlou9092@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research at Danesh Alborz University

Full name of responsible person

Saeid Shamlou Kazemi

Street address

Danesh Alborz University, Abyek

City

Abyek

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Qazvin

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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 President of Research at Danesh Alborz University

Proportion provided by this source

10

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

Bu-Ali Sina University

Full name of responsible person

Saeid Shamlou Kazemi

Position

Student

Latest degree

Master

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If the intellectual rights are preserved, the data can be sent to the researchers.

From where data/document is obtainable

Email address: saeidshamlou9092@gmail.com

What processes are involved for a request to access data/document

Submission of a written request (one week)

Comments