Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of combined exercises and the consumption of Mulberry leaf extract on the serum levels of alpha and beta salucin and some related inflammatory or cardiovascular markers in elderly men with type 2 diabetes

Protocol summary

Study aim

The effect of 8 weeks of combined exercises (aerobic and resistance) and the consumption of Mulberry leaf Extract on the serum levels of salusin alpha and beta and some cardiovascular inflammatory markers in elderly men with type 2 diabetes.

Design

The statistical population of the elderly with the age range of 60 to 70 years who referred to the diabetes center of Ardabil province. Phase 3. The sample size will be 40 people. Subjects will be placed in 5 groups, combined exercise group, exercise+supplement, supplement, placebo and control in a simple random manner and in pairs and individuals.

Settings and conduct

This study will be conducted as a 1-2 clinical trial. The combined training program (aerobic + resistance), for 8 weeks, will be three training sessions each week and each session will last 90 minutes with at least one day of rest between each session in the gym. Each training session includes a 10-minute warm-up period (including muscle stretching, walking) and aerobic exercises for 10 to 30 minutes with an intensity between 50 and 70% of the maximum strength, which will be calculated through the age-220 formula. After performing aerobic exercises, there is a rest between 3 and 5 minutes, and then resistance exercises are performed by the subjects for 30 to 40 minutes with an intensity between 40 and 70% of a maximum repetition. Resistance exercises include large upper body and lower body muscles, so that the participant can repeat each movement 8-12 times in each station.

Participants/Inclusion and exclusion criteria

Elderly men with type 2 diabetes

Intervention groups

Combined training group (aerobic + resistance), combined training group + supplement, complementary group, placebo group, control group

Main outcome variables

salucin alpha, salucin beta, interleukin 6, interleukin 1 beta, glucose, insulin, insulin resistance, galectin 3, lipocalin 2

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20201128049510N1**
Registration date: **2022-12-07, 1401/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-07, 1401/09/16**
Update count: **0**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name
Mohammad Ebrahim Bahram
Name of organization / entity
The University of Mohaghegh Ardabili
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-11-17, 1401/08/26
Expected recruitment end date
2023-02-15, 1401/11/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of combined exercises and the consumption of Mulberry leaf extract on the serum levels of alpha and beta salucin and some related inflammatory or cardiovascular markers in elderly men with type 2 diabetes

Public title
The effect of exercise and Mulberry leaf extract on some cardiovascular inflammatory markers in the elderly with type 2 diabetes
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having type 2 diabetes between one and 10 years Not taking more than one type of oral anti-diabetic pill at night Having a basic level of glycosylated hemoglobin between 6.6 and 9.9% Having a fasting blood glucose of 160 to 250 mg/dL Ability to do sports Not participating in a regular exercise program for at least 6 months before the start of the study
Exclusion criteria:
Taking more than one type of oral anti-diabetic pill at night Smoking having cardiovascular, kidney and eye diseases, complications of diabetes (neuropathy, nephropathy, retinopathy) Treated with insulin
Age
From **60 years** old to **70 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, the subjects are selected by simple random with the rule of random allocation. Thus, after determining the sample size, people will be equally placed in five groups (1-exercise, 2-exercise+supplement, 3- supplement, 4- placebo and 5-control). Using the lottery method, the names of the subjects are written on separate papers and placed in a container. Then the names of the subjects will be taken out randomly and they will be placed in the intervention, placebo and control groups respectively.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mohaghegh Ardabili University, Faculty of Educational Sciences and Psychology
Street address
Ardabil, University Street, University of Mohaghegh Ardabili
City
Ardabil
Province
Ardabil
Postal code
1136756199
Approval date
2022-04-25, 1401/02/05
Ethics committee reference number
IR.UMA.REC.1401.002

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Salusin alpha
Timepoint
24 hours before and 48 hours after training
Method of measurement
Blood sampling and using a laboratory kit

2

Description
Salusin beta
Timepoint
24 hours before and 48 hours after training

Method of measurement
Blood sampling and using a laboratory kit

3

Description
Lipocalin 2
Timepoint
24 hours before and 48 hours after training
Method of measurement
Blood sampling and using a laboratory kit

4

Description
Galectin 3
Timepoint
24 hours before and 48 hours after training
Method of measurement
Blood sampling and using a laboratory kit

5

Description
Interleukin 6
Timepoint
24 hours before and 48 hours after training
Method of measurement
Blood sampling and using a laboratory kit

6

Description
Interleukin 1 beta
Timepoint
24 hours before and 48 hours after training
Method of measurement
Blood sampling and using a laboratory kit

7

Description
Insulin
Timepoint
24 hours before and 48 hours after training
Method of measurement
Blood sampling and using a laboratory kit

8

Description
Glucose
Timepoint
24 hours before and 48 hours after training
Method of measurement
Blood sampling and using a laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1: Combined exercise (aerobic and resistance): Aerobic exercises will be performed for 10 to 30 minutes with an intensity between 50 and 70% of the maximum heart rate. Resistance exercises for 30 to 40 minutes with an intensity between 40 and 70 percent of a maximum repetition will be performed by the subjects.
Category
N/A

2

Description
Intervention group: Intervention group 2: Supplement group + daily exercise will consume 1000 mg (2 capsules of 500 mg), Mulberry leaf extract , 3 times a day along with combined exercises.
Category
N/A

3

Description
Intervention group: Intervention 3: The daily supplement group will take 1000 mg (2 capsules of 500 mg) of Mulberry leaf extract, 3 times a day.
Category
N/A

4

Description
Intervention group: Intervention 4: The placebo group will take 1000 mg daily (2 capsules of 500 mg), containing wheat flour, 3 times a day.
Category
N/A

5

Description
Control group: The control group will not participate in any exercise program.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
University of Mohaghegh Ardabili
Full name of responsible person
Mohammad Ebrahim Bahram
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Sponsors / Funding sources

1

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Name of organization / entity
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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
University of Mohaghegh Ardabili
Proportion provided by this source
20
Public or private sector
Public
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
University of Mohaghegh Ardabili
Full name of responsible person
Roghayyeh Afroundeh
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The personal data of the study participants can be shared after de-identification

When the data will become available and for how long

Three months after the results are published

To whom data/document is available

researchers

Under which criteria data/document could be used

In order to be more transparent and under the consent of the researcher

From where data/document is obtainable

Mohammad Ebrahim Bahram

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

Request and send to the researcher

Comments