

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Survey on the synergistic effect of some adiponectin gene polymorphisms in response to aerobic training with two different intensities in middle-aged men with type 2 diabetes

Protocol summary

Study aim

Determining the synergistic effect of adiponectin gene polymorphisms in response to aerobic exercise with different intensities in middle-aged men with type 2 diabetes

Design

A clinical trial of 150 diabetic patients, with control group and two parallel groups with different intensities of aerobic training interventions, randomized

Settings and conduct

In this study, which follows time-series pre and post-test design, 150 patients suffering from type 2 diabetes for more than 12 years and specified genotype of 5 Adiponectin gene polymorphisms are divided into three equal groups; one control and two intervention groups. Intervention groups will do aerobic exercise for 12 weeks and will be evaluated according to the genotype of each individual's response to the aerobic exercise. The study will be conducted at the Diabetes Clinic of Ardabil city.

Participants/Inclusion and exclusion criteria

inclusion criteria: A history of diabetes over 12 years, Glycated hemoglobin index above 7; Exclusion criteria: Having a diabetic foot ulcer during the study period, Having neurological and orthopedic disorders, Having severe retinopathy, Having regular physical activity for the past 6 months

Intervention groups

The aerobic exercise intervention groups A (n = 50) and B (n = 50) will do their exercises with the following intensities respectively: 50-65% and 65-80% the peak oxygen uptake. The intervention will last 12 weeks, three sessions per week, and 45 minutes per session. The control group, on the other hand, will not do any regular exercise. The peak oxygen uptake (Vo₂peak) will be determined using a modified Balke test on a treadmill.

Main outcome variables

Plasma adiponectin levels, Five polymorphisms of the

adiponectin gene

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200201046326N1**

Registration date: **2020-07-03, 1399/04/13**

Registration timing: **retrospective**

Last update: **2020-07-03, 1399/04/13**

Update count: **0**

Registration date

2020-07-03, 1399/04/13

Registrant information

Name

Elahe Mamashli

Name of organization / entity

University of Mohaghegh Ardabili

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-22, 1398/05/31

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

2019-08-22, 1398/05/31

Actual recruitment end date

2019-10-22, 1398/07/30

Trial completion date

2020-09-21, 1399/06/31

Scientific title

Survey on the synergistic effect of some adiponectin gene polymorphisms in response to aerobic training with two different intensities in middle-aged men with type 2 diabetes

Public title

The effect of different genotypes of adiponectin gene on diabetes response to exercise

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All diabetic patients who have more than 12 years history of diabetes Hemoglobin A1c above 7 Age under 65 years old

Exclusion criteria:

People with a history of cardiovascular disease and cancer Diabetic foot ulcer Having an amputation Severe retinopathy Having neurological and orthopedic disorders Having regular physical activity for the past 6 months

Age

From **45 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Actual sample size reached: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the total sample size of 150 people after screening was determined as the research sample, then using random allocation method, 50 balls were considered for the first intervention group, 50 balls for the second intervention group and another 50 balls for the control group. These balls were placed in a lottery container, then balls were randomly removed from the container without replacement and the sequence created was recorded

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 in Biomedical Research of Ardabil University of Medical Sciences

Street address

Research Ethics Committee, North side of Ardebil University of Medical Sciences, University Square, University Street

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Ardabil

Province

Ardabil

Postal code

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Approval date

2019-03-02, 1397/12/11

Ethics committee reference number

IR.ARUMS.REC.1397.287

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

Adiponectin

Timepoint

Before and after 12 weeks of aerobic exercise

Method of measurement

Adiponectin ELISA kit

2

Description

Five polymorphisms of the adiponectin gene

Timepoint

Before 12 weeks of aerobic exercise

Method of measurement

DNA extraction and pcr method

Secondary outcomes

1

Description

Hemoglobin A1c

Timepoint

Before and after 12 weeks of aerobic exercise

Method of measurement

Using the HbA1c kit and the enzyme method (Diazyme)

2

Description

Fasting blood sugar

Timepoint

Before and after 12 weeks of aerobic exercise

Method of measurement

Quantitative diagnostic kit (glucose oxidase), by enzymatic photometric method

3

Description

Low-density lipoprotein(LDL)

Timepoint

Before and after 12 weeks of aerobic exercise

Method of measurement

Relevant diagnostic kit, Enzymatic method

4

Description

High-density lipoprotein (HDL)

Timepoint

Before and after 12 weeks of aerobic exercise

Method of measurement

Relevant diagnostic kit, Enzymatic method

5

Description

Total Cholesterol

Timepoint

Before and after 12 weeks of aerobic exercise

Method of measurement

Relevant diagnostic kit, Enzymatic method

6

Description

Triglycerides

Timepoint

Before and after 12 weeks of aerobic exercise

Method of measurement

Relevant diagnostic kit, Enzymatic method

7

Description

blood pressure

Timepoint

Before and after 12 weeks of aerobic exercise

Method of measurement

Using a mercury sphygmomanometer

Intervention groups

1

Description

Intervention group 1: In this group, 50 diabetic patients perform low intensity aerobic exercise (65% of maximal oxygen consumption) for 12 weeks, 3 sessions per week. The content of a training session will include dynamic stretching movements in the warm-up (10 minute) and cool-down (7 minute) sections and Jogging for the main section (10 minute).The intensity and type of exercises are designed according to the standards and recommendations of the American College of Sports Medicine.

Category

Lifestyle

2

Description

Intervention group 2: In this group, 50 diabetic patients perform high intensity aerobic exercise (80% of maximal oxygen consumption) for 12 weeks, 3 sessions per week. The content of a training session will include dynamic stretching movements in the warm-up (10 minute) and cool-down (7 minute) sections and Jogging for the main section (10 minute). The intensity and type of exercises are designed according to the standards and recommendations of the American College of Sports Medicine.

Category

Lifestyle

3

Description

Control group: 50 diabetic patients who will not have regular exercise for 12 weeks.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil province diabetes clinic

Full name of responsible person

Dr. Iranparvar

Street address

Diabetes Clinic, End of Ochedkan Alley, Taleghani Street, Ardabil

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Sponsors / Funding sources

1

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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
The University of Mohaghegh Ardabili
Proportion provided by this source
50
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

2

Sponsor

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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
Ardabil University of Medical Sciences
Proportion provided by this source
50
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

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

No - There is not 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

Part of the data related to the distribution of the 5 polymorphisms studied will be shared.

When the data will become available and for how long

Start of access period 6 months after publication of Results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers in this field who have a larger statistical sample than our research

From where data/document is obtainable

Elahe Mamashli, PhD student of Mohaghegh Ardabili University, Mamashli.elahe@gmail.com 09115327323

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

After receiving the request, the data will be sent after informing the other participants in this research

Comments