

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of 8 weeks of endurance and resistance training on fibroblast growth factor 21 (FGF21) and insulin resistance in type 2 diabetic women.

Protocol summary

Study aim

Comparison of the effect of 8 weeks of endurance and resistance training on fibroblast growth factor 21(FGF21) and insulin resistance in type 2 diabetic women.

Design

Clinical practice with endurance group, resistance group and community-based control group, with parallel and random groups.

Settings and conduct

Before the beginning of the practice protocol, a session was organized for the subjects to familiarize with the exercises. Each training session starts with 10 minutes warming and ends up cooling for 10 minutes. The first group received aerobic exercise in the first two weeks for 20 minutes and with 50% heart rate, at the third and fourth week for 30 minutes with 50% heart rate, fifth and sixth weeks for 30 minutes with 60% heart rate and performs at 7th and 8th week for 35 minutes and with 60% heart rate. Resistance exercises are performed using bodybuilding machines in the first and second weeks in two sets and from the third week to the end of the course in three sets with 75% intensity of one maximum repetition.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having diabetes for more than a year; Having a low life; Use of hypoglycemic drugs; Non-compliance criteria: Having secondary complications of diabetes such as ocular complications, kidney problems; Having cardiovascular and inflammatory diseases; Having physical impairment.

Intervention groups

The endurance group, performs aerobic exercises for 8 weeks and three sessions per week. In the resistance group, the exercises perform with 75% intensity of one maximum repetition using bodybuilding machines. The control group does not have any training.

Main outcome variables

Insulin; Glucose; Insulin resistance; Fibroblast growth factor 21; Body fat percentage; Maximum Oxygen Consumption; Body composition (BMI);

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180721040542N1**

Registration date: **2018-10-15, 1397/07/23**

Registration timing: **retrospective**

Last update: **2018-10-15, 1397/07/23**

Update count: **0**

Registration date

2018-10-15, 1397/07/23

Registrant information

Name

Mahbobe Khorsand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5525 8277

Email address

M_khorsand2012@shahroodut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-30, 1395/10/10

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 8 weeks of endurance and resistance training on fibroblast growth factor 21 (FGF21) and insulin resistance in type 2 diabetic women.

Public title

The effect of endurance and resistance training on diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

According to a physician's diagnosis, they have more than one year of type 2 Diabetes Have a low mobility Use only Glucose-lowering drugs (Metformin)

Exclusion criteria:

Have be Secondary complications of diabetes, such as ocular, kidney complications Have be cardiovascular and inflammatory diseases Have a physical injury

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is that people based on finger blood glucose are divided into three groups. So that the average blood glucose in each group is similar.

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**

Shahroud University of Medical Sciences

Street address

Shahroud, Seventh Tir Square, Shahroud University of

Medical Sciences

City

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Province

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Postal code

36147-73947

Approval date

2018-07-02, 1397/04/11

Ethics committee reference number

IR.SHMU.REC.1397.071

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**

Fibroblast growth factor 21

Timepoint

Blood samples were taken at once in the first stage(pre-test) and secondly(post-test) after 8 weeks of exercise.

Method of measurement

Fibroblast growth factor factor 21 kit

2**Description**

Insulin resistance

Timepoint

Blood samples were taken once in the first stage(pre-test) and the second time(post-test) after 8 weeks of training.

Method of measurement

Formula for evaluation of insulin resistance homeostasis model(HOMA-IR)

Secondary outcomes**1****Description**

Glucose

Timepoint

Blood samples were taken once in the first stage (pre-test) and the second time (post-test) after 8 weeks of training.

Method of measurement

Glucose Kit and Colorimetric Enzymatic Method

2

Description

Insulin

Timepoint

Blood samples were taken once in the first stage (pre-test) and the second time (post-test) after 8 weeks of training.

Method of measurement

Insulin kit and Elisa method

Intervention groups

1

Description

The endurance group performed aerobic exercises in the first two weeks for 20 minutes at 50% heart rate, and at 3rd and 4th weeks for 30 minutes with 50% heart rate, and fifth and sixth weeks for 30 minutes with 60% heart rate and in the last two weeks, they perform for 35 minutes with 60% heart rate. To determine the intensity of exercise, the maximum heart rate was calculated with the formula of $220 - \text{age}$. Resilience group performed at the first session of resistance training for proper learning of movements, subjects with minimum weight and several sub-maximal repetitions. Then, resistance exercises were performed using bodybuilding machines in the first and second weeks in two sets, from the third week to the end. The course is carried out in three sets with an intensity of 75% one maximum repetition.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrood Diabetes Center

Full name of responsible person

Ali Hassani

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Shahrood, 22 Bahman Avenue, Shahid Madani Alley, in front of Rasoul Akram Doctors' Building

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Technology

Full name of responsible person

Mohammad Mehdi Fateh

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Shahrood Square, Haft-e-Tir Square, Shahrood University of Technology

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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

Shahrood University of Technology

Proportion provided by this source

100

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

Shahrood University of Medical Sciences

Full name of responsible person

Mahbobe Khorsand

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiology

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

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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