

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of concurrent training order on some mitochondrial, ribosome biogenesis regulatory myokines and insulin resistance in type 2 diabetes patient

Protocol summary

Study aim

Comparison the effect of concurrent training order on some mitochondrial, ribosome biogenesis regulatory myokines and insulin resistance in type 2 diabetes patient

Design

Randomized clinical trial, with control group and parallel exercises groups

Settings and conduct

The subjects will be trained in two training group for 12 weeks. The aerobic-resistance group will perform at first the aerobic protocol and then the resistance protocol. Resistance-aerobic exercise group will perform at first the resistance protocol and then the aerobic protocol. All steps will be measured at Ferdowsi University of Mashhad.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having type 2 Diabetes, Body mass index 28 to 35, Age 40 to 50 years Exclusion criteria: Using insulin, having other metabolic disorders in addition to type 2 diabetes, having regular physical activity in the last six months

Intervention groups

Experimental groups: The aerobic-resistance and resistance-aerobic training groups will practice for 12 weeks (three sessions per week). The training protocol is the same for the training groups, the only difference will be in the sequence of exercises. The control group will be community based and without exercise.

Main outcome variables

Myostatin, Follistatin, Insulin resistance, FGF21, Irisin, HbA1C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181002041204N1**

Registration date: **2019-02-25, 1397/12/06**

Registration timing: **retrospective**

Last update: **2019-02-25, 1397/12/06**

Update count: **0**

Registration date

2019-02-25, 1397/12/06

Registrant information

Name

Morteza Motahari Rad

Name of organization / entity

Ferdowsi University of Mashhad

Country

Iran (Islamic Republic of)

Phone

+98 51 3870 8915

Email address

motahari.rad@mail.um.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

2018-04-09, 1397/01/20

Actual recruitment end date

2018-05-10, 1397/02/20

Trial completion date

2018-10-07, 1397/07/15

Scientific title

The effect of concurrent training order on some

mitochondrial, ribosome biogenesis regulatory myokines and insulin resistance in type 2 diabetes patient

Public title

Effect of exercise on type 2 diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of Type 2 Diabetes (Fasting blood glucose greater than 126 mg/dL, Oral glucose tolerance test equal to or greater than 200 mg/dL, A1C level of 6.5 percent or higher) BMI 28-35 Age between 40-50 years

Exclusion criteria:

use insulin having cardiovascular diseases, musculoskeletal disorders, liver disease, kidney disease, thyroid dysfunction having regular physical activity in at least the last six months

Age

From **40 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization (random allocation rule) with using the SAS software

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 Ferdowsi University of Mashhad

Street address

Ferdowsi University of Mashhad, Azadi square.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948974

Approval date

2018-03-10, 1396/12/19

Ethics committee reference number

1397.016.IR.MUM.FUM.REC

2

Ethics committee

Name of ethics committee

Ethics committee Mahshad University of Medical Sciences

Street address

Mahshad University of Medical Sciences, Azadi square.

City

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Razavi Khorasan

Postal code

91778-99191

Approval date

2018-09-22, 1397/06/31

Ethics committee reference number

IR.MUMS.REC.1397.202

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Myostatin (MSTN)

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

ELISA method

2

Description

Follistatin (FSTL)

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

ELISA method

3

Description

Fibroblast Growth Factor 21 (FGF21)

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

ELISA method

4

Description

Irisin

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

ELISA method

5

Description

Insulin resistance

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

HOMA-IR method

6

Description

HbA1C

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

Nyco Card device

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: The aerobic-resistance group will exercise for 12 weeks and three sessions a week. The aerobic-resistance group will perform the aerobic protocol and then the resistance protocol during a training session. The aerobic exercise protocol is 1×10 minutes exercise with one minute active rest between the sets (with using treadmill). Resistance exercises include movements such as leg press, bench press, seated leg extension, lat pull down, lying leg curl, seated shoulder press, which there are include the main muscles of the lower trunk and upper trunk and they will be done by the machine.

Category

Prevention

2

Description

The second intervention group: The resistance-aerobic group will exercise for 12 weeks and three sessions a week. The resistance-aerobic group will perform the resistance protocol and then the aerobic protocol during a training session. The aerobic exercise protocol is 1×10 minutes exercise with one minute active rest between the sets (with using treadmill). Resistance exercises include movements such as leg press, bench press, seated leg extension, lat pull down, lying leg curl, seated shoulder press, which there are include the main muscles of the lower trunk and upper trunk and they will be done by the machine.

Category

Prevention

3

Description

Control group: community-based and untrained.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Parsian Diabetes Clinic

Full name of responsible person

Aliakbar Raouf Saeb

Street address

chamran 8, emam reza square.

City

Mashhad

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9144583392

Phone

+98 51 3223 6843

Email

dr.raoof@yahoo.com

Web page address

<http://www.parsiandiabetes.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ferdowsi University of Mashhad

Full name of responsible person

Nahid Bijeh

Street address

Ferdowsi University of Mashhad, Azadi square.

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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

Ferdowsi University of Mashhad

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

Ferdowsi University of Mashhad

Full name of responsible person

Nahid Bijeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Faculty of Sport Sciences, Ferdowsi University of Mashhad, Azadi square.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ferdowsi University of Mashhad

Full name of responsible person

Nahid Bijeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ferdowsi University of Mashhad

Full name of responsible person

Morteza Motahari Rad

Position

Ph.D student

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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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

Yes - There is 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

The whole data is potentially shared after unidentified individuals.

When the data will become available and for how long

The beginning of the data access period is 6 months after the publication of the articles.

To whom data/document is available

The data will be accessible only to researchers working in academic institutions.

Under which criteria data/document could be used

The data will be available as generally and non publication by the recipient.

From where data/document is obtainable

To receive research information, send an email to Reihane.nejati@gmail.com.

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

Data will be sent after obtaining permission from the project manager.

Comments