

# 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

Mashhad

##### Province

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

##### **Province**

Razavi Khorasan

##### **Postal code**

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.

##### **City**

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bijeh@um.ac.ir

**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

**Street address**

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**

Exercise Physiology

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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

**Street address**

Faculty of Sport Sciences, Ferdowsi University of Mashhad, Paradise Daneshgah, Azadi Square.

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**Fax**

**Email**

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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**