

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of twelve weeks combined exercise training on insulin resistance and some metabolic factors in type II diabetic patients

Protocol summary

Study aim

Comparison of the effect of twelve weeks combined exercise training on insulin resistance and some metabolic factors in type 2 diabetic patients

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

Insulin resistance, GLP-1, HbA1C, SGOT, ALP, SGPT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190128042529N1**

Registration date: **2019-02-21, 1397/12/02**

Registration timing: **retrospective**

Last update: **2019-02-21, 1397/12/02**

Update count: **0**

Registration date

2019-02-21, 1397/12/02

Registrant information

Name

Reihaneh Nejati

Name of organization / entity

Ferdowsi university of mashhad

Country

Iran (Islamic Republic of)

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+98 51 3870 8915

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re.nejati@mail.um.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-05-10, 1397/02/20

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 twelve weeks combined exercise training on insulin resistance and some metabolic factors in type II diabetic patients

Public title

The 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

Randomization will be performed by the SAS software and every patient will be entered in the exercise 1, exercise 2 or control group.

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**

Ferdowsi University of Mashhad

Street address

Ferdowsi University of Mashhad, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

91177948974

Approval date

2018-04-19, 1397/01/30

Ethics committee reference number

IR.MUM.FUM.1397.030

2**Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences

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Mashhad University of Medical Sciences, Azadi square.

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Postal code

9919191778

Approval date

2018-09-22, 1397/06/31

Ethics committee reference number

IR.MUMS.REC.1397.205

Health conditions studied**1****Description of health condition studied**

Type II diabetes mellitus

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

insulin resistance

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

HOMA-IR method

2**Description**

Glucagon-like peptide-1 (GLP-1)

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

ELISA method

3**Description**

HbA1C

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

Nyco Card device

4**Description**

ALP

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

spectrophotometry method

5

Description

Aspartate aminotransferase (SGOT or AST)

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

spectrophotometry method

6

Description

Alanine aminotransferase (SGPT or ALT)

Timepoint

Before the intervention and 48 hours after the end of intervention

Method of measurement

spectrophotometry method

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.

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9144583392

Phone

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Email

dr.raoof@yahoo.com

Web page address

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research Ferdowsi University of Mashhad

Full name of responsible person

Seyyed Reza Attarzadeh Hosseini

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ferdowsi university of mashhad, Azadi Square.

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attarzadeh@um.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research 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
Seyyed Reza Attarzadeh Hosseini
Position
Professor
Latest degree
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Other areas of specialty/work
Sport Physiology
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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
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

All analyzes and all data

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