Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of effect of selective aerobic training on insulin resistance, blood glucose level and serum leptin in male patients with diabetes type 2

Protocol summary

Summary

Objectives: Survey of effecting of selective aerobic training on insulin resistance, blood glucose level and serum Leptin in male patients with diabetes type 2 , Design: Not blinded randomized clinical trial Setting and conduct: 60 diabetic patients will be divided to the intervention group that will be done aerobic exercise, and the control group that will not be done aerobic exercise Major Inclusion and Exclusion criteria: Inclusion criteria: type II diabetic patients; men; age between 30 to 50 years Exclusion criteria: women; persons under 30 and over 50 years Intervention: in the intervention group exercise will be done with intensity equivalent heart rate 70-60%, on the ergometer bicycle and treadmill for 12 weeks, 3 sessions per week , 60 minutes per session and in the control group will not exercise program Main outcome measures (variablesof): insulin, glucose and leptin level of blood

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016011822583N4**
Registration date: **2016-02-23, 1394/12/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-23, 1394/12/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Esfarayen Faculty of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of effect of selective aerobic training on insulin resistance, blood glucose level and serum leptin in male patients with diabetes type 2

Public title

Effect of selective aerobic training on insulin resistance and serum leptin in patients given to diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: type II diabetic patients; men; age between 30 to 50 years Exclusion criteria: women; persons under 30 and over 50 years

Age

From **30 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Sabzevar University of Medical Sciences

Street address

Razavi Khorasan, Sabzevar, Road of Shahrood, Sabzevar University of Medical Sciences

City

Sabzevar

Postal code

Approval date

2015-10-31, 1394/08/09

Ethics committee reference number

1394.89.IR.MEDSAB.REC

Health conditions studied

1

Description of health condition studied

Diabetes Type II

ICD-10 code

(E11)

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Leptin of serum

Timepoint

3 months after intervention

Method of measurement

Evaluation of blood serum

2

Description

Blood glucose

Timepoint

3 months after intervention

Method of measurement

Evaluation of blood serum

3

Description

Insulin level

Timepoint

3 months after intervention

Method of measurement

Evaluation of blood

Secondary outcomes

1

Description

Triglycerides

Timepoint

3 months after intervention

Method of measurement

Evaluation of blood serum

2

Description

Blood pressure

Timepoint

3 months after intervention

Method of measurement

Clinical observation

Intervention groups

1

Description

In the intervention group exercise will be done with intensity equivalent heart rate 70-60%, on the ergometer bicycle and treadmill for 12 weeks, 3 sessions per week , 60 minutes per session.

Category

Lifestyle

2

Description

The control group will not exercise program.

Category

N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Parsian Diabetes Center
Full name of responsible person
Mahdi Esmaeilizadeh
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Parsian Diabetes Center, Vakilabad Boulevard, Mashhad, Razavi Khorasan
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Sponsors / Funding sources

1

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
Vice chancellor for research of Esfarayen Faculty of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty