

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effect of 12-week aerobic interval training on endothelial function and serum levels of Adropin in type 2 diabetic women

Protocol summary

Study aim

Effect of 12 weeks of high-intensity interval training on flow-mediated dilation and circulating levels of adropin and nitrite / nitrate levels in women with type 2 diabetes

Design

Thirty women with type 2 diabetes are randomly divide into intervention and control groups, and randomization is performed by block randomization.

Settings and conduct

Thirty patients with type 2 diabetes are selected based on the criteria for entering the study from the Diabetes Clinic of Sanandaj (Iran). Flow mediated dilation, Serum adropin levels, Plasma nitrite/nitrate levels, lipid profile, glycosylated hemoglobin, plasma insulin levels, fasting blood glucose and anthropometric characteristics are measure before and after the 12 weeks intervention in both groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria including age range 20 to 44 years, more than 2 years history of type 2 diabetic, fasting blood glucose more than 125mg/dl and and no exercise training in the previous 6 months before the study:

Criteria for not entering the study including glycosylated hemoglobin more than 10%, insulin therapy and having any chronic disease other than type 2 diabetic

Intervention groups

The intervention group performe high-intensity interval training for 12 weeks, three sessions per week and each session including four 4-min interval at 85-95% of HRmax and 3-min active recovery at 50-60% of HRmax. Control group maintain their daily activities and does not participate in any exercise-training program.

Main outcome variables

Flow Mediated Dilation; Serum adropin levels; Plasma nitrite/nitrate levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200412047039N1**

Registration date: **2020-05-07, 1399/02/18**

Registration timing: **retrospective**

Last update: **2020-05-07, 1399/02/18**

Update count: **0**

Registration date

2020-05-07, 1399/02/18

Registrant information

Name

Shiva Abdi

Name of organization / entity

The University of Razi

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 3612

Email address

shiva.abdi101@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-17, 1398/05/26

Expected recruitment end date

2019-11-13, 1398/08/22

Actual recruitment start date

2019-08-17, 1398/05/26

Actual recruitment end date

2019-11-13, 1398/08/22

Trial completion date

2019-11-13, 1398/08/22

Scientific title

Effect of 12-week aerobic interval training on endothelial function and serum levels of Adropin in type 2 diabetic

women

Public title

Effect of Interval Training on endothelial function

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Fasting blood glucose levels more than 125 mg/dL
Age range 20 to 44 years
More than 2 years history of type 2 diabetic
No exercise training in the previous 6 months before the study

Exclusion criteria:

HbA1c more than 10%
Insulin therapy
Having any chronic disease other than type 2 diabetic

Age

From **20 years** old to **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible participants were randomly divided into two groups: high-intensity interval training and control. Randomization was performed by block randomization with a block size of two (Based on age and body mass index).

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 Kermanshah University of Medical Sciences

Street address

Central building of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

IR.KUMS.REC.1397.933

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

Flow Mediated Dilation

Timepoint

Before and after 12 weeks exercise training

Method of measurement

Doppler ultrasound system

2

Description

Serum adipon levels

Timepoint

Before and after 12 weeks exercise training

Method of measurement

ELISA method

3

Description

Plasma nitrite/nitrate levels

Timepoint

Before and after 12 weeks exercise training

Method of measurement

Griess method

Secondary outcomes

1

Description

Lipid profile

Timepoint

Before and after the 12 weeks exercise training

Method of measurement

Enzymatic method

2

Description

Glycosylated hemoglobin

Timepoint

Before and after the 12 weeks exercise training

Method of measurement

Chromatography method

3

Description

Plasma insulin levels

Timepoint

Before and after the 12 weeks exercise training

Method of measurement

ELISA method

4

Description

Fasting blood glucose

Timepoint

Before and after the 12 weeks exercise training

Method of measurement

Enzymatic method

5

Description

Body Mass Index

Timepoint

Before and after the 12 weeks exercise training

Method of measurement

Weight in kilograms divided by height in meters squared

6

Description

Waist-Hip ratio

Timepoint

Before and after the 12 weeks exercise training

Method of measurement

Meter

7

Description

Body fat percentage

Timepoint

Before and after the 12 weeks exercise training

Method of measurement

Using Jackson-Pollock 3-spot formula by a Caliper

Intervention groups

1

Description

Intervention group: exercise training program performs three times a week for 12 weeks. Each exercise session consist of 10-min of warm up at 40% heart rate maximum(HRmax) and 25 minutes of running on treadmill, including four four-minute interval at 85-95% of HRmax and 3 minutes at 50-60% of HRmax and end with a 5 minutes cool down at 40% of HRmax.

Category

Rehabilitation

2

Description

Control group: No exercise intervention are performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Touhid Hospital Diabetes Clinic of Sanandaj

Full name of responsible person

Street address

Touhid Hospital, Basij Street

City

Sanandaj

Province

Kurdistan

Postal code

00000000000

Phone

+98 87 3328 6112

Email

shiva.abdi101@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Razi

Full name of responsible person

Vahid Tadibi

Street address

Razi University, Taq-e Bostan, Kermanshah

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Kermanshai

Province

Kermanshah

Postal code

6714414971

Phone

+98 83 3427 7605

Email

info@razi.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

The University of Razi

Proportion provided by this source

100

Public or private sector

Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
The University of Razi
Full name of responsible person
Shiva Abdi
Position
Student
Latest degree
Master
Other areas of specialty/work
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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 data of the participating participants will be encrypted and will be published with the privacy of the patient and the confidentiality of the information.
When the data will become available and for how long
The date of access to the data is six months after the publication of the results.
To whom data/document is available
Only available to scholars working in academic and academic institutions
Under which criteria data/document could be used
The requirements for access to data include the sending of documents relating to the applicant's membership in academic and academic institutions, and the applicant is authorized to use this data in order to document for subsequent studies.
From where data/document is obtainable
You can use the email address to access the information:

shiva.abdi101@yahoo.com

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

The applicant will send the data to him at least one

month later by sending valid credentials to members of the academic and research institutes at the email address of the author.

Comments