Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 adropin 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
City
Kermanshai
Province
Kermanshah
Postal code
۶۷۱۴۴۱۴۹۷۱
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

Others

Street address

Directorate General of Kurdistan welfare, Shebli Blvd

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Sanandaj

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Person responsible for updating data

Contact

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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