Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of interval training on nitric oxide level and insulin resistance and some of cardiometabolic risk factors in type 2 diabetes patients

Protocol summary

Summary

(1) Objective: The aim of this study is to investigate the interval training effectiveness on nitric oxide level and insulin resistance and some of cardiometabolic risk factors in type 2 diabetes patients. (2) Design: This study is a randomized controlled trial (3) Setting and conduct: This study will be done at endocrinology clinic of Karaj Rajaee hospital. Eligible subjects will randomly receive one of the following treatments; interval training exercise and usual physical activity. (4) Participants including major eligibility criteria: This clinical trial will be carry out on 30 female patients with type 2 diabetes and aged 40 to 55 years. (5) Intervention: thrity patients with type 2 diabetes will be assigned randomly into two groups and receive one of the following two interventions; 15 patients will receive interval training exercise with 18 sessions (three sessions per week), and 15 patients in control group will have usual physical activity. Each training session lasts 25 minutes and consists a single set of exercise with 10 time repetitions. Training will be perform on a cycle ergometer set in constant watt mode at a pedal cadence of 80 to 100 revolutions/min. Each repetition of the training takes 60 seconds and there will be a 60 seconds recovery period between each repetition. Each training session include a 3 min warm up and 2 min cooldown. All patients will receive regular routine diabetes care throughout the study. (6) Main outcome measures: The variables will be measured before and 24 to 72 hours after completing all training sessions: blood pressure, anthropometric measurements (body weight, height,), nitric oxide, fasting blood sugar, insulin resistance, glycosylated haemoglobin (HbA1C), fasting total cholesterol (TC), high-density lipoprotein (HDL), low-density lipoprotein (LDL) and triglyceride (TG)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082835945N1**
Registration date: **2017-10-30, 1396/08/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-30, 1396/08/08

Registrant information

Name
Tahereh Arefirad
Name of organization / entity
Islamic Azad University, Science And Research Branch
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Alborz University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of interval training on nitric oxide level and insulin

resistance and some of cardiometabolic risk factors in type 2 diabetes patients

Public title
Effect of interval training in diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Female patients between 40 to 55 years; patients diagnosed with type 2 diabetes mellitus; Not taking insulin for treatment; Baseline glycosylated hemoglobin (HbA1c) values of 53 and 75 mmol/mol (7 to 9%); No previous exercise training in the last 6 months. Exclusion criteria: Patients diagnosed with nephropathy; retinopathy and/or severe neuropathy associated to diabetes; Patients diagnosed with severe cardiovascular or cerebrovascular diseases.
Age
From **40 years** old to **55 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
School of Medicine, Alborz University of Medical Sciences, Baghestan Boulevard, Karaj, Iran.
City
Karaj
Postal code
Approval date
2017-06-10, 1396/03/20
Ethics committee reference number
abzums.rec.1396.48

Health conditions studied

1

Description of health condition studied
diabetes
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
fasting blood sugar
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
mg/dl

2

Description
Nitrit
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
µmol/l

3

Description
Insulin level
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
mU/l

Secondary outcomes

1

Description
Glycosylated Haemoglobin (HbA1C)
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
Percent

2

Description
Total Cholesterol
Timepoint
Before and 24 to 72 hours after completing all training sessions

Method of measurement
mg/dl

3

Description
High density lipoprotein (HDL)
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
mg/dl

4

Description
Low density lipoprotein (LDL)
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
mg/dl

5

Description
Triglyceride (TG)
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
mg/dl

6

Description
Body weight
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
Kg

7

Description
Diastolic blood pressure
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
ml/Hg

8

Description
Systolic blood pressure
Timepoint
Before and 24 to 72 hours after completing all training sessions
Method of measurement
ml/Hg

Intervention groups

1

Description
Intervention group: patients will receive interval training exercise with 18 sessions (three sessions per week). Each training session lasts 25 minutes and consists a single set of exercise with 10 time repetitions. Training will be perform on a cycle ergometer set in constant watt mode at a pedal cadence of 80–100 revolutions/min. Each repetition of the training takes 60 seconds and there will be a 60 seconds recovery pried between each repetition. Each training session include a 3-min warm-up and 2-min cool-down at 50 W for a total of 25 min.
Category
Lifestyle

2

Description
Control group: patients will have usual physical activity.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology Clinic of Karaj Rajaee Hospital
Full name of responsible person
Taherh Arefirad
Street address
Shahid Rajaee Street, Shahid Beheshti Street, Karaj, Alborz Province
City
Karaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Alborz University of Medical Sciences
Full name of responsible person
Mostafa Qorbani
Street address
Alborz University of Medical Sciences, Baghestan Boulevard, Karaj, Iran.
City
Karaj
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 Alborz University 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

Contact

Name of organization / entity

Islamic Azad University،Science And Research Branch

Full name of responsible person

Tahereh Arefirad

Position

PhD

Other areas of specialty/work

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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