

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Rajaei 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: thirty 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8866 3344

###### Email address

tahereharefyrad@yahoo.com

##### 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 Rajae Hospital

**Full name of responsible person**

Taherh Arefirad

**Street address**

Shahid Rajae 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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**Web page address**

**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*