Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

The effect of a submaximal alternative exercise program on heart rate variability profile (HRV), selected resting echocardiographic factors and presentation of multivariate predictive clinical regression model in boys with type 1 diabetes

Protocol summary

Study aim
Presenting a predictive linear / nonlinear regression model for diagnostic estimation of cardiac autonomic function in T1DM patients

Design
The study included 2 groups of type 1 diabetics and one healthy group (12 people in each group). 24 diabetic patients were randomly selected from all patients in the province and were divided into two groups of 12 under the supervision of a specialist physician (consultant professor) in a simple random method. Control groups including a group of 12 type 1 diabetics and a group of 12 healthy peers were monitored in the study.

Settings and conduct
First, anthropometric variables and patient history characteristics are measured from their medical records, especially the daily dose of the drug. Boys participate in the sub-maximal aerobic periodic exercise program for 8 consecutive weeks with an average of 65% of the telemetry reserve rate, each morning workout on the grass and outdoor sports gradually from 30 to 60 minutes below the lactate threshold. The main stages of work in the two stages before and after the intervention are aerobic exercise program

Participants/Inclusion and exclusion criteria
24 eligible boys 12 to 18 years with a history of more than 2 years with type 1 diabetes and glycosylated hemoglobin level of 6% and above, and 12 healthy boys

Intervention groups
Sub-maximal aerobic intermittent exercise program for 12 consecutive weeks with an average of 65% telemetry reserve rate Control groups: a group of 12 people with type 1 diabetes and a group of 12 healthy peers

Main outcome variables
FBS , HbA1C TG, TC, LDL-C, HDL-C NEP, EP Measuring the structure and function of the heart T base practical capacity, heart rate variability (HRV)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211031052926N1**
Registration date: **2021-11-13, 1400/08/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-13, 1400/08/22**
Update count: **0**

Registration date
2021-11-13, 1400/08/22

Registrant information

Name
hossein saki

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2021-12-22, 1400/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of a submaximal alternative exercise program on heart rate variability profile (HRV), selected resting echocardiographic factors and presentation of multivariate predictive clinical regression model in boys with type 1 diabetes

Public title
The effect of exercise program intervention on diabetes
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Type 1 diabetic boys in the age range of 12 to 18 years Having Hba1c more than 6% History of at least 2 years of diabetes
Exclusion criteria:
Symptoms of diabetic neuropathy, cerebrovascular or ocular diseases, and respiratory failure Taking certain medications other than insulin Taking drugs that affect resting heart rate High blood pressure Have regular exercise during the week
Age
From **12 years** old to **18 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The study included two groups of type 1 diabetics and one healthy group. Exercise intervention is performed only on one diabetic group. The other diabetic group and the healthy group are controls.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamedan University of Medical Sciences
Street address
Hamedan. Shahid Ahmadi Boulevard clear. Bu Ali Sina University. Faculty of Physical Education and Sport Sciences
City
Hamedan
Province
Hamadan
Postal code
6793137396
Approval date
2021-10-20, 1400/07/28
Ethics committee reference number
IR.BASU.REC.1400.040

Health conditions studied

1

Description of health condition studied
Type 1 diabetes
ICD-10 code
E10
ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
Epinephrine hormone (EP)
Timepoint
Baseline and final (12th week)
Method of measurement
Blood samples test

2

Description
Norepinephrine hormone (NEP)
Timepoint
Baseline and final (12th week)
Method of measurement
Blood samples test

3

Description
Glycated hemoglobin (HbA1c)
Timepoint
Baseline and final (12th week)
Method of measurement
Blood samples test

4

Description
Fasting blood sugar (FBS)

Timepoint
Baseline and final (12th week)
Method of measurement
Blood samples test

5

Description
High-density lipoprotein (HDL) cholesterol
Timepoint
Baseline and final (12th week)
Method of measurement
Blood samples test

6

Description
low-density lipoprotein (LDL) cholesterol
Timepoint
Baseline and final (12th week)
Method of measurement
Blood samples test

7

Description
Triglyceride (TG)
Timepoint
Baseline and final (12th week)
Method of measurement
Blood samples test

8

Description
Total Cholesterol (TC)
Timepoint
Baseline and final (12th week)
Method of measurement
Blood samples test

9

Description
Dimensions of aorta (AO)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (M-mode)

10

Description
Dimensions of left atrium (LA)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (M-mode)

11

Description
right ventricle lateral wall (RV)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (M-mode)

12

Description
left ventricular internal dimension during diastole (LVIDd)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (M-mode)

13

Description
left ventricular internal dimension during systole (LVIDs)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (M-mode)

14

Description
inter ventricular septum (IVS)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (M-mode)

15

Description
Posterior ventricular wall thickness (PW)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (M-mode)

16

Description
Fractional shortening (FS)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (M-mode)

17

Description
Ventricular ejection fraction (EF)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (M-mode)

18

Description
tricuspid velocity in the initial flow of diastole (E tricuspid)
Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (pulsed wave)

19

Description

tricuspid velocity during active atrial contraction (A tricuspid)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (pulsed wave)

20

Description

Deceleration time, from maximum point E to baseline (DT tricuspid)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (pulsed wave)

21

Description

mitral velocity in the initial flow of diastole (E mitral)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (pulsed wave)

22

Description

mitral velocity during active atrial contraction (A mitral)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (pulsed wave)

23

Description

Deceleration time, from maximum point E to baseline (DT mitral)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (pulsed wave)

24

Description

Wave S right ventricle (’RV-S)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (tissue Doppler)

25

Description

Wave A right ventricle (RV-A’)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (tissue Doppler)

26

Description

Wave E right ventricle (RV-E’)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (tissue Doppler)

27

Description

right ventricle isovolumic contruction time (RV-ICT)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (tissue Doppler)

28

Description

right ventricle isovolumic relaxation time (RV-IRT)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (tissue Doppler)

29

Description

right ventricle myocardial performance index (RV-MPI)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (tissue Doppler)

30

Description

The ratio of the maximum systolic velocity to the initial right ventricular diastolic flow velocity (RV-E/E’)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (tissue Doppler)

31

Description

The ratio of the maximum systolic velocity to the initial left ventricular diastolic flow velocity (LV-E/E’)

Timepoint

Baseline and final (12th week)

Method of measurement

Echocardiography (tissue Doppler)

32

Description
left ventricle myocardial performance index (LV-MPI)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (tissue Doppler)

33

Description
left ventricle isovolumic relaxation time (LV-IRT)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (tissue Doppler)

34

Description
left ventricle isovolumic contruction time (LV-ICT)
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (tissue Doppler)

35

Description
Wave E left ventricle (LV-E')
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (tissue Doppler)

36

Description
Wave A left ventricle (LV-A')
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (tissue Doppler)

37

Description
Wave S left ventricle (LV-S')
Timepoint
Baseline and final (12th week)
Method of measurement
Echocardiography (tissue Doppler)

38

Description
The functional capacity of the heart
Timepoint
Baseline and final (12th week)
Method of measurement
Exercise test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intermittent exercise program includes a combination of strength and sub-maximal aerobic exercise for twelve consecutive weeks with an average of 65% heart rate, telemetry, each morning workout on grass and outdoor sports gradually from 30 to 60 minutes below lactate threshold and at a safe level with Supervised by instructors and consultants. The first week includes: 5 minutes of warm-up, 15 minutes of flexibility exercises, 10 minutes of strength exercises (3 to 10 sets of different movements with the individual's own body weight) 10 minutes of aerobic exercise with 50% heart rate reserve 5 minutes of cooling (30 minutes HRR) with an intensity of 50%. Over 12 weeks, 5 minutes of flexibility exercises, 15 minutes of strength exercises (3 to 10 sets of upper and lower body exercises with weights and stretching), 35 minutes of intermittent aerobic exercise with 70 to 75% reserve heart rate (50-55). Minutes with an intensity of 70% HRR).
Category
Prevention

2

Description
The diabetic group continued their daily activities, including recreational and sports activities, in addition to regular aerobic and resistance activities in sports venues.
Category
Early detection

3

Description
This healthy group continued their daily activities, including recreational and sports activities, in addition to regular aerobic and resistance activities in sports venues.
Category
Early detection

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Cardiovascular Hospital
Full name of responsible person
Farnaz Fariba
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Hamedan. Shahid Ahmadi Roshan Boulevard. Bu Ali Sina University. Faculty of Physical Education and Sports Sciences

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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
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Hossein Saki
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Latest degree
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Other areas of specialty/work
Physiology
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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Blood data, exercise test and echo and Holter

When the data will become available and for how long
11401 onwards

To whom data/document is available
Research results are published for everyone's use

Under which criteria data/document could be used
To help patients, their families, doctors and sports coaches

From where data/document is obtainable
Research results are published for everyone's use

What processes are involved for a request to access data/document
Research results are published for everyone's use

Comments