

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of combined exercise training on inflammatory factors and levels of hormones associated with blood glucose homeostasis in pediatric type 1 diabetes

#### Protocol summary

##### Study aim

Effect of combined exercise training on inflammatory factors and levels of hormones associated with blood glucose homeostasis in pediatric type 1 diabetes

##### Design

In this research, 35 child With type 1 diabetes voluntarily will be divided into two groups; 20 people in experimental and 15 people in control group.

##### Settings and conduct

The present study is a semi-experimental study among the child With type 1 diabetes of city of Rasht for 16 weeks. Blood sampling is performed after 12 hours of fasting and before and after 16 weeks of concurrent training.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having age ranges of 8-15 years,  $A1c \geq 7$ , Pediatric type 1 diabetes, No regular exercise  
Exclusion criteria: more than three session absence from the training

##### Intervention groups

Intervention group: Combined training group. Aerobic training: sixteen weeks, three times per week . Aerobic exercises were performed with an intensity of 50-75% of maximum heart rate, pilates exercises, 3 set, 6-12 repeat and training using body weight with 20 minuets.  
Control group: Without intervention

##### Main outcome variables

IL-1B, HS-CRP, IGF-1, Grows hormone, Cortisol, HbA1c, FBS, CBC

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150531022498N30**  
Registration date: **2019-07-26, 1398/05/04**

Registration timing: **retrospective**

Last update: **2019-07-26, 1398/05/04**

Update count: **0**

##### Registration date

2019-07-26, 1398/05/04

##### Registrant information

###### Name

Ramin Shabani

###### Name of organization / entity

Islamic Azad University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3375 2715

###### Email address

shabani@iaurasht.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-09, 1397/11/20

##### Expected recruitment end date

2019-07-22, 1398/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of combined exercise training on inflammatory factors and levels of hormones associated with blood glucose homeostasis in pediatric type 1 diabetes

##### Public title

Effect of combined exercise training in pediatric type 1 diabetes

IR.IAU.RASHT.REC.1398.011

## **Purpose**

Prevention

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Having age ranges of 8-15 years A1c $\geq$ 7 Pediatric type 1 diabetes No regular exercise

### **Exclusion criteria:**

More than three session absence from the training

## **Age**

From **8 years** old to **15 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **35**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Subjects were divided into 2 groups (one control group and one experimental groups) using the simple random method. This sampling will be done based on the red and blue balls inside the box that are randomly taken by the subjects (Red Orb and the Blue Orb of the experimental group).

## **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 Islamic Azad University Rasht Branch

##### **Street address**

Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

##### **City**

Rasht

##### **Province**

Guilan

##### **Postal code**

۴۱۴۷۶۵۴۹۱۹

#### **Approval date**

2019-07-19, 1398/04/28

#### **Ethics committee reference number**

### 2

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Islamic Azad University Rasht Branch

##### **Street address**

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##### **City**

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##### **Province**

Guilan

##### **Postal code**

۴۱۴۷۶۵۴۹۱۹

#### **Approval date**

2017-09-19, 1396/06/28

#### **Ethics committee reference number**

IR.IAU.RASHT.REC.1396.168

## **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**

IL-1B

#### **Timepoint**

Before and after the end of interventions

#### **Method of measurement**

using ELISA Kit

### 2

#### **Description**

High-sensitivity C-reactive Protein (hs-CRP)

#### **Timepoint**

Before and after the end of interventions

#### **Method of measurement**

using ELISA Kit

### 3

#### **Description**

IGF-1

#### **Timepoint**

Before and after the end of interventions

#### **Method of measurement**

using ELISA Kit

#### 4

**Description**

Growth hormone

**Timepoint**

Before and after the end of interventions

**Method of measurement**

using ELISA Kit

#### 5

**Description**

Cortisol

**Timepoint**

Before and after the end of interventions

**Method of measurement**

using ELISA Kit

#### 6

**Description**

HbA1c

**Timepoint**

Before and after the end of interventions

**Method of measurement**

using ELISA Kit

#### 7

**Description**

Fast blood sugar

**Timepoint**

Before and after the end of interventions

**Method of measurement**

using ELISA Kit

#### 8

**Description**

Complete Blood Count (CBC)

**Timepoint**

Before and after the end of interventions

**Method of measurement**

using ELISA Kit

### Secondary outcomes

#### 1

**Description**

Quality of Life

**Timepoint**

Before and after the end of interventions

**Method of measurement**

Using questionnaire

#### 2

**Description**

Body composition

**Timepoint**

Before and after the end of interventions

**Method of measurement**

Using weight, body mass index, waist to hip ratio and fat percent

#### 3

**Description**

Physical fitness

**Timepoint**

Before and after the end of interventions

**Method of measurement**

Using measurement of aerobic power ,anaerobic , balance ,Flexibility and hand grip

#### 4

**Description**

Blood pressure

**Timepoint**

Before and after the end of interventions

**Method of measurement**

Using the blood pressure device

### Intervention groups

#### 1

**Description**

Intervention group: Combined training group. Aerobic training: sixteen weeks, three times per week . Aerobic exercises were performed with an intensity of 50-75% of maximum heart rate ,pilates exercises, 3 set, 6-12 repeat and training using body weight with 20 minuets.

**Category**

Lifestyle

#### 2

**Description**

Control group: Without intervention

**Category**

Lifestyle

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

17 Shahrivar Children's Hospital

**Full name of responsible person**

Dr setila dalili

**Street address**

Shahid Siadati Avenu, Namjoo Street, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4147654919

**Phone**

+98 13 3336 9070

**Email**

marzieh.nazari.v@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Ali delpasand

**Street address**  
Islamic Azad University, Rasht Branch

**City**  
Rasht

**Province**  
Guilan

**Postal code**  
۴۱۴۷۶۵۴۹۱۹

**Phone**  
+98 13 3342 2153

**Email**  
shabani\_msn@yahoo.com

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**  
Islamic Azad University

**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**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Marzieh Nazari

**Position**  
PhD student

**Latest degree**  
Master

**Other areas of specialty/work**  
Exercise physiology

**Street address**  
Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

**City**  
Rasht

**Province**  
Guilan

#### Postal code

4147654919

#### Phone

+98 13 3342 2153

#### Email

marzieh.nazari.v@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Dr Ramin shabani

**Position**  
Associate Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Exercise physiology

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Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

**City**  
Rasht

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4147654919

**Phone**  
+98 13 3342 2153

**Email**  
shabani\_msn@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Islamic Azad University

**Full name of responsible person**  
Marzieh Nazari

**Position**  
PhD Student

**Latest degree**  
Master

**Other areas of specialty/work**  
Exercise physiology

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**Email**  
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## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

### **Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

### **Statistical Analysis Plan**

Not applicable

## **Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

### **Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

### **Analytic Code**

Not applicable

### **Data Dictionary**

Not applicable