# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jul 2026

## Comparison of the effect of resistance and aerobic training on the expression of microRNA-192 and serum levels of GLP-1, GABA, Pentraxin3 and HbA1c in children with type 1 diabetes

### Protocol summary

**Study aim**
Evaluation of the effect of exercise training on effective biomarkers in type 1 diabetes
**Design**
The clinical trial consists of four groups of 15 volunteers to compare the effect of the two training methods.
**Settings and conduct**
Exercises will be done at home under the supervision of a exercise physiologist. At the beginning and end of the eight-week training period, blood samples and physiological measurements will be performed to evaluate the effect of exercise.
**Participants/Inclusion and exclusion criteria**
Having type 1 diabetes; Lack of regular exercise in the last year; No physical injury or limited mobility
**Intervention groups**
Regular exercise for eight weeks
**Main outcome variables**
Helping patients with type 1 diabetes recover by recognizing the beneficial effects of exercise

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20200326046861N2**
Registration date: **2022-05-14, 1401/02/24**
Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**
Update count: **0**
**Registration date**
2022-05-14, 1401/02/24

**Registrant information**
**Name**
Vazgen Minasian
**Name of organization / entity**
University of Isfahan
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3627 8066
**Email address**
v.minasian@spr.ui.ac.ir

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2022-07-06, 1401/04/15
**Expected recruitment end date**
2022-09-06, 1401/06/15
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the effect of resistance and aerobic training on the expression of microRNA-192 and serum levels of GLP-1, GABA, Pentraxin3 and HbA1c in children with type 1 diabetes

**Public title**
Effect of exercise on some serum factors in children with type 1 diabetes
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Type 1 diabetes at least one year after diagnosis
**Exclusion criteria:**

Diseases that prevent people from participating in exercising activities.

**Age**
To **18 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**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 Isfahan University

**Street address**
University of Isfahan, Azadi square, Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673441

**Approval date**
2022-03-14, 1400/12/23

**Ethics committee reference number**
IR.UI.REC.1400.115

## Health conditions studied

### 1

**Description of health condition studied**
type 1 diabetes

**ICD-10 code**
E08

**ICD-10 code description**
Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

**Description**
Investigation of changes in microRNA-192

**Timepoint**
Before and after the eight-week period of exercise

**Method of measurement**
PCR

### 2

**Description**
Evaluation of changes in GLP-1 protein in serum

**Timepoint**
Before and after the eight-week period of exercise

**Method of measurement**
ELISA

### 3

**Description**
Evaluation of changes in GABA protein in serum

**Timepoint**
Before and after the eight-week period of exercise

**Method of measurement**
ELISA

### 4

**Description**
Evaluation of changes in Pentraxin3 protein in serum

**Timepoint**
Before and after the eight-week period of exercise

**Method of measurement**
ELISA

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group 1: It consists of a group of 15 members with a resistance exercise protocol (exercises at home, with minimal exercise equipment and involving different muscle groups in the body) which is performed for 8 weeks and 3 days a week for 1 hour. Subjects will not use any medications or dietary supplements during the eight weeks of exercise other than the medications prescribed by their physician.

**Category**
Lifestyle

### 2

**Description**
Intervention group 2: It consists of a group of 15 members with aerobic exercise protocol (exercises at

home, with minimal exercise equipment) which is performed for 8 weeks and 3 days a week for 1 hour. Subjects will not use any medications or dietary supplements during the eight weeks of exercise other than the medications prescribed by their physician.

**Category**
Lifestyle

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Imam Hossien Children's Hospital
**Full name of responsible person**
Silva Hovsepian
**Street address**
Metabolic Liver Disease Research Center, Imam Hossien Children's Hospital, Isfahan University of Medical Sciences, Isfahan
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Phone**
+98 913 129 4269
**Email**
silvahovsepsecret@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
University of Isfahan
**Full name of responsible person**
Vazgen Minasian
**Street address**
University of Isfahan, Azadi square, Isfahan
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673441
**Phone**
+98 913 202 0396
**Email**
v.minasian@spr.ui.ac.ir

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
University of Isfahan
**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**
University of Isfahan
**Full name of responsible person**
Maryam Nazari
**Position**
Postdoctoral researcher
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Physiology
**Street address**
University of Isfahan, Azadi square, Isfahan
**City**
Isfehan
**Province**
Isfehan
**Postal code**
8174673441
**Phone**
+98-313-7932003-7
**Email**
m.nazari1320@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
University of Isfahan
**Full name of responsible person**
Maryam Nazari
**Position**
Postdoctoral researcher
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Physiology
**Street address**
University of Isfahan, Azadi square, Isfahan
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673441
**Phone**
+98 31 3793 2571
**Email**
m.nazari1320@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
University of Isfahan

**Full name of responsible person**
Maryam Nazari

**Position**
Postdoctoral researcher

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Physiology

**Street address**
University of Isfahan, Azadi square, Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673441

**Phone**
+98 31 3793 2571

**Email**
m.nazari1320@yahoo.com

## 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**
All blood and physiological data of individuals can be shared after they were made anonymous.

**When the data will become available and for how long**
The start of the access period will be 6 months after the publication of the results.

**To whom data/document is available**
For researchers and scientific journals

**Under which criteria data/document could be used**
Researchers and scientific journals can access the data if they make their reports in coordination with us and mention the names of the main authors of this study in their report.

**From where data/document is obtainable**
Applicants can contact the corresponding or other authors via email.

**What processes are involved for a request to access data/document**
Applicants can submit their application via email. Information will be provided to them in case of authors' agreement.

**Comments**