

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

Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

City

Rasht

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

Street address

Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

City

Rasht

Province

Guilan

Postal code

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

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

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