Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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≥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

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Ramin Shabani

Name of organization / entity
Islamic Azad University

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Iran (Islamic Republic of)

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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

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Having age ranges of 8-15 years A1c≥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
IR.IAU.RASHT.REC.1398.011

2

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University Rasht Branch

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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
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marzieh.nazari.v@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ali delpasand
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Islamic Azad University, Rasht Brunch
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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
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Marzieh Nazari
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Exercise physiology
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Person responsible for updating data

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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