Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of concurrent aerobic-resistance training on T4 , TSH, blood lipids, leptin, cortisol, blood glucose homeostasis, and physical fitness in girls with hypothyroidism

Protocol summary

Study aim
The effect of concurrent aerobic-resistance training on T4 , TSH, blood lipids, leptin, cortisol, blood glucose homeostasis, and physical fitness in girls with hypothyroidism

Design
Randomized clinical trial with control group, non blinded, with parallel groups

Settings and conduct
The present research is a semi-experimental study on patients with with hypothyroid in 17 shahrivar Hospital in Rasht , after the introduction of Endocrinologist will participate in exercise training three days a week for 8 weeks. Aerobic training is at 60 to 70% of maximum heart rate) and resistance exercise using Bodybuilding machine with an intensity of 40 to 65% of 1RM. Blood sampling is performed before and after eight weeks of training.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Girls with hypothyroid Having age range 60 to 75 years Not having exercise training

Intervention groups
Experimental group: Combined exercises including aerobic training (at 60 to 70% of maximum heart rate) and resistance exercise (using Bodybuilding machine with an intensity of 40 to 65% of 1RM) Control group: Without intervention

Main outcome variables
T4, FSH, blood glucose homeostasis, blood lipids

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150531022498N26**
Registration date: **2018-10-25, 1397/08/03**
Registration timing: **retrospective**

Last update: **2018-10-25, 1397/08/03**
Update count: **0**

Registration date
2018-10-25, 1397/08/03

Registrant information

Name
Ramin Shabani

Name of organization / entity
Islamic Azad University

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-04-19, 1395/01/31

Expected recruitment end date
2016-06-20, 1395/03/31

Actual recruitment start date
2016-04-19, 1395/01/31

Actual recruitment end date
2016-06-20, 1395/03/31

Trial completion date
2016-06-20, 1395/03/31

Scientific title
The effect of concurrent aerobic-resistance training on T4 , TSH, blood lipids, leptin, cortisol, blood glucose homeostasis, and physical fitness in girls with hypothyroidism

Public title
The effect of concurrent aerobic-resistance training in girls with hypothyroidism
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Girls with hypothyroid Having age range 60 to 75 years Not having exercise training
Exclusion criteria:
Patients with psychiatric and nervous disorders who are being treated with sedative medicines Patients with orthopedic, verbal and auditory problems
Age
From **8 years** old to **15 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Actual sample size reached: **20**
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 Rasht Azad University
Street address
Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht
City
Rasht
Province
Guilan
Postal code
4147654919
Approval date
2017-01-17, 1395/10/28
Ethics committee reference number
IR.IAU.RASHT.REC.1395.59

2

Ethics committee
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Street address
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Postal code
4147654919
Approval date
2016-08-18, 1395/05/28
Ethics committee reference number
IR.IAU.RASHT.REC.1395.23

Health conditions studied

1

Description of health condition studied
Hypothyroidism
ICD-10 code
E03
ICD-10 code description
Other hypothyroidism

Primary outcomes

1

Description
TSH
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using ELISA Kit

2

Description
T4
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using ELISA Kit

3

Description
Leptin
Timepoint
Before and after the end of 8 weeks of training
Method of measurement

using ELISA Kit

4

Description
Cortisol
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using ELISA Kit

5

Description
Fasting Blood glucose
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using ELISA Kit

6

Description
Insulin
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using ELISA Kit

7

Description
low density lipoprotein
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using ELISA Kit

8

Description
High density lipoprotein
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using ELISA Kit

9

Description
Cholstrol
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using ELISA Kit

10

Description
Triglyceride
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using ELISA Kit

11

Description
HOMA
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
Using Insulin Resistance Formula

Secondary outcomes

1

Description
Rest Metabolism Rate
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using Mifflin formula

2

Description
Anaerobic power
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
using RAST test

3

Description
Aerobic power
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
Using shuttle run

4

Description
Power
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
Using Force Gauges

5

Description
Body composition
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
Using by measurement of weight, body mass index (BMI), fat percent, fat free mass and waist circumference

Intervention groups

1

Description
Intervention group: Eight weeks of concurrent resistance

and aerobic exercises with 3 sessions per week will be done. Aerobic exercise including aerobic running with an intensity of 60 to 70% of maximum heart rate will be conducted. Resistance exercises are done using Bodybuilding machine with an intensity of 40 to 65% of 1RM

Category
Prevention

2

Description
Control group: Without intervention

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
17 Shahrivar Children's Hospital

Full name of responsible person
Dr Setila Dalili

Street address
Opposite the City Park, Siadati Av., Namjo Ave., Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Rasht 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
Masomeh Amani

Position
Student

Latest degree
Master

Other areas of specialty/work
Others

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Person responsible for scientific inquiries

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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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The study was not completed

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available