

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

Phone

+98 13 3375 2715

Email address

shabani@iaurasht.ac.ir

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****Name of ethics committee**

Ethics committee of Rasht Azad University

Street address

Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

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Province

Guilan

Postal code

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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

Cholesterol

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

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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

Ali Delpasand

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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**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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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Marzieh Nazari

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Exercise physiology

Street address

Rasht Branch, Islamic Azad University, Taleshan
Bridge

City

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