

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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**

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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**

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

**Street address**

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

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**Province**

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**Phone**

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**Email**

shabani\_msn@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ali Delpasand

**Street address**

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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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**Email**

amanisetare@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

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marzieh.nazari.v@gmail.com

## 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