

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Effect of aerobic and resistance training on body composition, glucose homeostasis, appetite, serum leptin and hs-CRP levels in over weight and obese anxious girls

#### Protocol summary

##### Study aim

Assessing the effect of concurrent aerobic and resistance training on body composition, resting energy expenditure, serum lipid, leptin, cortisol, growth, prolactin hormones, appetite, glucose homeostasis, sleep quality, aerobic and an aerobic power and Hs-CRP levels in over weight and obese anxious girls

##### Design

In this research, 30 overweight and obese anxious girls voluntarily will be divided into two groups; 15 people in experimental and 15 people in control group.

##### Settings and conduct

The present study is a semi-experimental study among the students of city of Rasht for 8 weeks. Blood sampling is performed after 12 hours of fasting and before and after eight weeks of aerobic and resistance training.

##### Participants/Inclusion and exclusion criteria

Aged of 14-17 years, not have regular exercise training during last year, not have orthopedic disease

##### Intervention groups

Intervention (concurrent training) group: Includes resistance and aerobic training for eight weeks Control group :no intervention

##### Main outcome variables

Blood lipid, Leptin, Cortisol, Resting energy expenditure , Prolactin , Grow hormones, Blood glucose , Insulin , Appetite , CRP-hs, sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150531022498N16**

Registration date: **2018-01-28, 1396/11/08**

Registration timing: **retrospective**

Last update: **2018-01-28, 1396/11/08**

Update count: **0**

##### Registration date

2018-01-28, 1396/11/08

##### 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

Vice Chancellor of Research, University of Islamic Azad University, Rasht Branch

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of aerobic and resistance training on body composition, glucose homeostasis, appetite, serum leptin and hs-CRP levels in over weight and obese anxious girls

##### Public title

Effect of aerobic and resistance training in over weight and obese anxious girls

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Aged of 14-17 years Not have regular exercise training during last year not have orthopedic disease

##### **Exclusion criteria:**

Absence for more than three sessions of training have special diet

#### **Age**

From **14 years** old to **17 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **30**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **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 Azad University, Rasht Branch

###### **Street address**

Islamic Azad University, Rasht Branch

###### **City**

Rasht

###### **Province**

Guilan

###### **Postal code**

۴۱۴۷۶۵۴۹۱۹

###### **Approval date**

2017-09-19, 1396/06/28

###### **Ethics committee reference number**

IR.IAU.RASHT.REC.1396.91

#### **2**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Azad University, Rasht Branch

##### **Street address**

Islamic Azad University, Rasht Branch

##### **City**

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##### **Province**

Guilan

##### **Postal code**

۴۱۴۷۶۵۴۹۱۹

##### **Approval date**

2017-09-19, 1396/06/28

##### **Ethics committee reference number**

IR.IAU.RASHT.REC.1395.79

#### **3**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Azad University, Rasht Branch

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###### **Postal code**

۴۱۴۷۶۵۴۹۱۹

###### **Approval date**

2017-09-19, 1396/06/28

###### **Ethics committee reference number**

IR.IAU.RASHT.REC.1396.80

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Obesity

##### **ICD-10 code**

E66.0

##### **ICD-10 code description**

Obesity due to excess calories

### **Primary outcomes**

#### **1**

##### **Description**

Blood lipid

##### **Timepoint**

Before and eight weeks after the exercise

##### **Method of measurement**

Serum levels using ELISA method (mg/dl)

#### **2**

##### **Description**

Leptin

##### **Timepoint**

Before and eight weeks after the exercise

##### **Method of measurement**

Serum levels using ELISA method (ng/ml)

### 3

**Description**

cortisol

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

serum levels using ELISA method ( $\mu\text{g/dl}$ )

### 4

**Description**

Resting energy expenditure

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

According to equations

### 5

**Description**

Prolactin

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

Serum levels using ELISA method ( $\text{ng/ml}$ )

### 6

**Description**

Growth hormone

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

blood sampling ELISA

### 7

**Description**

Blood glucose

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

serum levels using photometric method ( $\text{mg/dl}$ )

### 8

**Description**

Insulin

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

serum levels using ELISA method ( $\text{pmol/L}$ )

### 9

**Description**

Appetite

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

Using appetite questionnaire

### 10

**Description**

hs-CRP

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

serum levels using ELISA method ( $\text{ng/mL}$ )

### 11

**Description**

sleep quality

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

Using questionnaire

## Secondary outcomes

### 1

**Description**

Body mass index

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

Using of Weight on squared height formula

### 2

**Description**

Aerobic power

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

Using of Racport.

### 3

**Description**

Anaerobic power

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

Using of Rast test

### 4

**Description**

percentage of body fat

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

Using of caliper and by body fat percent formula

### 5

**Description**

Body mass without fat

**Timepoint**

Before and eight weeks after the exercise

**Method of measurement**

Using of caliper.

## Intervention groups

### 1

#### Description

Intervention group: Concurrent training aerobic and resistance for 8 weeks.

#### Category

Prevention

### 2

#### Description

Control group: no intervention

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Somayeh School of Rasht

##### Full name of responsible person

Zohreh Nikjoo

##### Street address

Lakan gate, Azad university of rasht,Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

4147654919

##### Phone

+98 13 3342 2153

##### Email

Zohreh\_\_nikjoo@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Ali delpasand

##### Street address

Lakan gate, Azad University of rasht,Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

4147654919

##### Phone

+98 13 3342 3308

##### 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

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Zohreh Nikjo, Donya sajadi, Marjan zahmatkesh

##### Position

Student

##### Latest degree

Master

##### Other areas of specialty/work

Exercise Physiology

##### Street address

Islamic Azad University Rasht Branch, Lakan Bridge, Rasht

##### City

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##### Province

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##### Postal code

4147654919

##### Phone

+1 333422153

##### Fax

##### Email

marzieh.nazari.v@gmail.com

##### Web page address

## 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

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Marzieh Nazari

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Exercise Physiology

**Street address**

Islamic Azad University Rasht Branch, Lakan Bridge,  
Rasht

**City**

Rasht

**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**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available