

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Impact of a short-term period of intensive aerobic exercise training and green tea consumption on body composition and inflammatory parameters in sedentary young men

#### Protocol summary

##### Study aim

Impact of a short-term period of intensive aerobic exercise training and green tea consumption on body composition and inflammatory parameters in sedentary young men

##### Design

Randomized clinical trial with control group, with 38 participants

##### Settings and conduct

The present research is a semi-experimental study on sedentary young men in Gilan University of Medical Sciences which will participate in exercise training three days a week for 4 weeks. Aerobic training is at 55 to 85% of maximum heart rate. Blood sampling is performed before and after four weeks of training.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Sedentary young men, Not having having exercise training Inclusion criteria: Patients with psychiatric and nervous disorders who are being treated with sedative medicine Patients with orthopedic, verbal and auditory problems

##### Intervention groups

Intervention group 1: Exercise training: Fourth weeks of aerobic exercises with 3 sessions per week will be done. Aerobic exercise including running on treadmill with an intensity of 55 to 85% of maximum heart rate will be conducted. Intervention group 2: green tea group: eight weeks, three time training combine with daily consumption of 3 pills of green tea containing 441 mg of polyphenol. Intervention group 3: Aerobic training combine with green tea consumption: Eight weeks, three time training (Similar to aerobic training group) combine with daily consumption of 3 pills of green tea containing 441 mg of polyphenol. Control group: Without intervention

##### Main outcome variables

Creatine phosphokinase (CPK), lactate dehydrogenase

(LDH), Body composition

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150531022498N28**

Registration date: **2018-11-11, 1397/08/20**

Registration timing: **retrospective**

Last update: **2018-11-11, 1397/08/20**

Update count: **0**

##### Registration date

2018-11-11, 1397/08/20

##### 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

2016-05-20, 1395/02/31

##### Expected recruitment end date

2016-07-21, 1395/04/31

##### Actual recruitment start date

2016-05-20, 1395/02/31

##### Actual recruitment end date

2016-07-21, 1395/04/31  
**Trial completion date**  
2016-07-21, 1395/04/31

### Scientific title

Impact of a short-term period of intensive aerobic exercise training and green tea consumption on body composition and inflammatory parameters in sedentary young men

### Public title

Impact of aerobic exercise training and green tea consumption in sedentary young men

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Not having exercise training sedentary young men

#### Exclusion criteria:

Patients with psychiatric and nervous disorders who are being treated with sedative medicine Patients with orthopedic, verbal and auditory problems

### Age

From **18 years** old to **20 years** old

### Gender

Male

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **38**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Subjects were divided into 4 groups using the simple random method. This sampling will be done based on the colorful balls inside the box that are randomly taken by the subjects.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

### Assignment

Factorial

### 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

2016-04-18, 1395/01/30

### Ethics committee reference number

IR.IAU.RASHT.REC.1395.40

## Health conditions studied

### 1

#### Description of health condition studied

sedentary

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Creatine phosphokinase (CPK)

#### Timepoint

Before and after four weeks

#### Method of measurement

By Bionik kit

### 2

#### Description

lactate dehydrogenase (LDH)

#### Timepoint

Before and after four weeks

#### Method of measurement

By Bionik kit

## Secondary outcomes

### 1

#### Description

Body composition

#### Timepoint

Before and after four weeks

#### Method of measurement

Using by measurement of weight, body mass index (BMI), fat percent, fat free mass and waist and hip circumference

## Intervention groups

### 1

#### Description

Intervention group 1: Exercise training: Fourth weeks of aerobic exercises with 3 sessions per week will be done. Aerobic exercise including running on treadmill with an

intensity of 55 to 85% of maximum heart rate and for 30 minutes will be conducted.

**Category**

Prevention

**2**

**Description**

Intervention group 2: green tea group: eight weeks, daily consumption of 3 pills of green tea containing 441 mg of polyphenol.

**Category**

Prevention

**3**

**Description**

Intervention group 3: Aerobic training combine with green tea consumption: Eight weeks, three time training. Aerobic exercise including running on treadmill with an intensity of 55 to 85% of maximum heart rate and for 30 minutes combine with daily consumption of 3 pills of green tea containing 441 mg of polyphenol.

**Category**

Prevention

**4**

**Description**

Control group: Without intervention

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Gilan University of Medical Sciences

**Full name of responsible person**

Doctor Shahrokh Yousefzadeh-Chabok

**Street address**

Tehran Road, Guilan University of Medical Sciences, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4147654919

**Phone**

+98 13 3332 6065

**Email**

m\_nazari1390@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ali Delpasand

**Street address**

Rasht Branch, Islamic Azad University, Taleshan Bridge

**City**

Rasht

**Province**

Guilan

**Postal code**

4147654919

**Phone**

+98 13 3342 2153

**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**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Meysam pourmohamadi

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Exercise physiology

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**Email**

shabani\_msn@yahoo.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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**Province**

Guilan

**Postal code**

4147654919

**Phone**

+98 13 3342 2153

**Email**

shabani\_msn@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Marzieh Nazari

**Position**

PhD students

**Latest degree**

Master

**Other areas of specialty/work**

Exercise physiology

**Street address**

Rasht Branch, Islamic Azad University, Taleshan Bridge

**City**

Rasht

**Province**

Guilan

**Postal code**

4147654919

**Phone**

+98 13 3342 2153

**Email**

marzieh.nazari.v@gmail.com

## 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**

No decision has been made yet.

**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