

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effects of aerobic-resistance training combine with green coffee consumption on insulin-like growth factor-1 (IGF-1), leptin, testosterone, cortisol, insulin resistance, glucose homeostasis, heart rate, metabolism, body composition, physical fitness, general health, appetite, anxiety and depression in overweight and obese women

Protocol summary

Summary

The purpose of this study will be to evaluate the effect of aerobic-resistance training combine with green coffee consumption on Insulin-like growth factor-1, leptin, testosterone, cortisol, insulin resistance, glucose homeostasis, heart rate, metabolism, body composition, physical fitness, general health, appetite, anxiety and depression in overweight and obese women. Inclusion criteria consist of having age ranges 25 to 35 years old and not have metabolic or orthopedic disease and exclusion criteria will be consist of do not regular conduct of study interventions. In line with this, through overweight and obese women of Rasht city, 30 volunteers will be selected and randomly assigned into three groups and each group consist of 10 persons including: aerobic-resistance training, green coffee and aerobic- resistance training combine with green coffee. The study duration will be 6 weeks and green coffee and aerobic- resistance combine with green coffee groups will get 250 mg green coffee per day. Also, exercise program will be including of four sessions of aerobic- resistance training per week. Fasting blood sample will be taken 24 hour pre and post intervention for evaluating serum levels of IGF-1, leptin, testosterone, cortisol, insulin and fasting blood sugar.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061422498N13**

Registration date: **2017-06-21, 1396/03/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-21, 1396/03/31

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

Private

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of aerobic-resistance training combine with green coffee consumption on insulin-like growth factor-1 (IGF-1), leptin, testosterone, cortisol, insulin resistance,

glucose homeostasis, heart rate, metabolism, body composition, physical fitness, general health, appetite, anxiety and depression in overweight and obese women

Public title

Effects of aerobic-resistance training combine with green coffee consumption in overweight and obese women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: aged of 25-35 years; not have regular exercise training during last year; not have metabolic or orthopedic disease Exclusion criteria: using weight loss supplements or drug over the last six month; have special diet; absence for more than three sessions of training; not regular usage of green coffee

Age

From **25 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Islamic Azad University Rasht Branch

Street address

Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

City

Rasht

Postal code

Approval date

2017-01-17, 1395/10/28

Ethics committee reference number

IR.IAU.RASHT.REC.1395.66

Health conditions studied

1

Description of health condition studied

Overweight and obese women

ICD-10 code

E66.0, E66

ICD-10 code description

Obesity due to excess calories, Obesity, unspecified

Primary outcomes

1

Description

Insulin-like growth factor-1 (IGF-1)

Timepoint

24 hour before and after interventions

Method of measurement

Serum levels using ELISA method (ng/ml)

2

Description

Leptin

Timepoint

24 hour before and after interventions

Method of measurement

serum levels using ELISA method (ng/ml)

3

Description

Testosterone

Timepoint

24 hour before and after interventions

Method of measurement

serum levels using photometric method (µg/dl)

4

Description

Cortisol

Timepoint

24 hour before and after interventions

Method of measurement

serum levels using ELISA method (µg/dl)

5

Description

Fasting blood suger

Timepoint

24 hour before and after interventions

Method of measurement

serum levels using photometric method (mg/dl)

6

Description

Insulin

Timepoint

24 hour before and after interventions

Method of measurement

serum levels using ELISA method (pmol/L)

Secondary outcomes

1

Description

Insulin resistance

Timepoint

Before intervention and six weeks after intervention

Method of measurement

Using HOMA formula

2

Description

Heart rate

Timepoint

Before intervention and six weeks after intervention

Method of measurement

Using measurement of resting heart rate, systole and diastole blood pressure

3

Description

Basal and resting metabolic

Timepoint

Before intervention and six weeks after intervention

Method of measurement

Using BMR and RMR formula

4

Description

Body composition

Timepoint

Before intervention and six weeks after intervention

Method of measurement

Using measurement of weight, body mass index, body fat percent and waist to hip ratio

5

Description

Physical Fitness

Timepoint

Before intervention and six weeks after intervention

Method of measurement

Using measurement of aerobic power and anaerobic power

6

Description

General health

Timepoint

Before intervention and six weeks after intervention

Method of measurement

Using general health questionnaire

7

Description

Appetite

Timepoint

Before intervention and six weeks after intervention

Method of measurement

Using appetite questionnaire

8

Description

Anxiety and depression

Timepoint

Before intervention and six weeks after intervention

Method of measurement

Using questionnaire

Intervention groups

1

Description

Aerobic- resistance training Four sessions per week, each session consist of 20-30 min aerobic training at 65-75 percent of maximum heart rate and following that eight movement at 65-80 percent of one repetition maximum

Category

Prevention

2

Description

Green coffee Six weeks, two 125 mg serving per day, dissolving in hot water

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht city, Advertising

Full name of responsible person

Sajedeh Movaghary

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Rasht Branch

Full name of responsible person

Ali Delpasand

Street address

Islamic Azad University Rasht Branch, Taleshan

Bredge, Rasht
City
 Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Islamic Azad University Rasht Branch
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact
Name of organization / entity
 Islamic Azad University Rasht Branch
Full name of responsible person
 Nafiseh Karimnezhad, Zivar Hasani, Afshin Saket
Position
 MA
Other areas of specialty/work
Street address
 Islamic Azad University Rasht Branch, Taleshan
 Bredge, Rasht
City
 Rasht
Postal code
Phone
 +98 13 3375 2715
Fax
Email
 dr.ramin.shabani@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Islamic Azad University Rasht Branch
Full name of responsible person
 Dr Ramin Shabani
Position

Associate Professor
Other areas of specialty/work
Street address
 Islamic Azad University Rasht Branch, Taleshan
 Bridge, Rasht
City
 Rasht
Postal code
Phone
 +98 13 3375 2715
Fax
Email
 dr.ramin.shabani@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
 Islamic Azad University Rasht Branch
Full name of responsible person
 Fatemeh Izaddoust
Position
 MA
Other areas of specialty/work
Street address
 Islamic Azad University Rasht Branch, Taleshan
 Bridge, Rasht
City
 Rasht
Postal code
Phone
 00
Fax
Email
 fa.izaddoust@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty