

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of 8 weeks of High Intensity Interval Training with supplemental Ellagic acid on serum levels of some oxidative and antioxidant factors in obese women.

Protocol summary

Study aim

The Effect of 8 Weeks of Intense Interval Training and Oalic Acid Supplementation on Oxidative and Antioxidant Factors in Obese Women

Design

A controlled clinical trial with a randomized

Settings and conduct

Islamic Azad University Research Sciences Branch was conducted in 4 groups of 8 people (HIIT group, LA group, HIIT + LA group and control group) by 32 obese women between 30 and 30 45 years with BMI greater than 30 kg / m 2 were performed. At first, the conditions and the manner of performing the interventions were explained, then the informed consent form was filled out by the subjects. Height, weight, age and health status of the subjects were obtained before intervention. Blood samples were also taken before the intervention and 12 hours fasting. The main protocol of intense intermittent exercise was 4-minute 4-minute interval running in 95-95% HRpeak with 3 minutes walking in 50-60% HRpeak and 7 minutes. Rest is accompanied, they did. This protocol was derived from the study of Zhang et al. (2015). In this study Placebo (cerlac) or oleic acid (98%) was administered once daily for 8 weeks at 50 mg (one capsule). 48 hours after the end of blood transfusions, serum levels of GPx, MDA and TAC were measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Lowest weight change in the last 6 months, no disease, BMI greater than 30 and no exclusion criteria: Pregnancy and breastfeeding during study, antioxidant and fat burning supplements and medications

Intervention groups

High Intensity interval training (HIIT), Ellagic Acid supplementasion (LA), HIIT+ LA

Main outcome variables

Serum Glutathione Peroxidase (GPx), Malondialdehyde

(MDA) and Total Oxidative Capacity (TAC) Serum Levels as Dependent Variables and Intense Periodic Exercise and Supplementation of Oalic Acid as Dependent Variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191020045170N1**

Registration date: **2019-12-16, 1398/09/25**

Registration timing: **retrospective**

Last update: **2019-12-16, 1398/09/25**

Update count: **0**

Registration date

2019-12-16, 1398/09/25

Registrant information

Name

Marjan Mansouri dara

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4425 4085

Email address

ledig72@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

2019-03-11, 1397/12/20
Actual recruitment end date
2019-03-18, 1397/12/27
Trial completion date
2019-07-09, 1398/04/18

Scientific title
Effect of 8 weeks of High Intensity Interval Training with supplemental Ellagic acid on serum levels of some oxidative and antioxidant factors in obese women.

Public title
The effect of exercise and supplementation of ellagic acid on obesity

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having weight changes of less than 2kg in the last 6 months Body mass index (BMI) greater than 30 kg / m²
No history of any bone, cardiovascular, respiratory, liver, kidney, brain or hormonal disease Women in districts 1-6 of Tehran Age range between 30 and 45 years

Exclusion criteria:

Alcohol and cigarette consumption a week before the protocol Pre-protocol skeletal injuries Sensitivity to supplement or placebo Having a medical prohibition letter about exercise or supplementation Pregnancy or lactation

Age

From **30 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomized, individual, sealed envelopes

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

Sport Sciences Research Institute of Iran

Street address

Tehran Province, Tehran, District 7, 5th Dead End

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.SSRC.REC.1398.005

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

serum levels of GPx

Timepoint

Before intervention and 48 hours after intervention
(Exercise and supplementation)

Method of measurement

Colorimetric GPX assay kit, abcam 102530, Germany

2

Description

Malondialdehyde (MDA)

Timepoint

Before intervention and 48 hours after intervention
(Exercise and supplementation)

Method of measurement

Colorimetric MDA assay Kit, abcam 118970, Germany

3

Description

Total antioxidant capacity serum level

Timepoint

Before intervention and 48 hours after intervention
(Exercise and supplementation)

Method of measurement

Using FRAP method and 592 nm wavelength spectrophotometer using ELISA (Merckodia, Sweden)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: High Intensity Interval Training (8 weeks / three days a week) and 4-minute interval runs in 95-85% HRpeak followed by 3 minutes walking in 50-60% HRpeak and 7 minutes rest.

Category

Other

2

Description

Intervention group: Ellagic Acid Supplementation: Dosage is based on previous sources of 50 mg (one capsule / once daily for 8 weeks). This is a supplement made by the US supplement spot company.

Category

Other

3

Description

Intervention group: HIIT+LA: combined two intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University of Science Research

Full name of responsible person

Marjan Mansoori Dara

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Islamic Azad University of Science Research

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Ghazalian

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Faculty of Physical Education and Sport Sciences

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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

80

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

Marjan Mansoori Dara

Position

Student

Latest degree

Master

Other areas of specialty/work

Exercise Physiology

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MA student

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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 more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable