

# 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 / m<sup>2</sup>  
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

##### Street address

Islamic Azad University of Science Research

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۷۷۸۹۳۸۵۵

##### Phone

+98 21 4486 5179

##### Email

ledig72@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Farshad Ghazalian

##### Street address

Faculty of Physical Education and Sport Sciences

Islamic Azad University Research Sciences Branch

##### City

Tehran

##### Province

Tehran

##### Postal code

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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

##### Street address

Faculty of Physical Education and Sport Sciences  
Islamic Azad University Research Sciences Branch

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

**Full name of responsible person**

Marjan Mansoori Dara

**Position**

MA student

**Latest degree**

Master

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Marjan Mansoori Dara

**Position**

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