

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Effect of antioxidant rich formula supplementation and aerobic training on glutathione peroxidase and superoxide dismutase activity, determination of HSP-70 expressing mRNA and oxidative stress in female athletes

#### Protocol summary

##### Summary

Objectives: The aim of this study is to investigate the effect of antioxidant rich formula supplementation and aerobic training on glutathione peroxidase and superoxide dismutase activity, determination of HSP-70 expressing mRNA and oxidative stress in female athletes. Design: This study is a double blind study. Setting, conduct and intervention: Volunteers will randomly assigned to two groups (antioxidant rich formula/semi-formula). Weight, height, body fat percent and dietary intake (3-day food record questionnaire) will be assessed. The first blood sampling will be held before the exercise test (Astrand test), and the second and third blood sampling will be held 1 and 24 hours after the test, respectively. After 4 weeks intervention (supplements and aerobic exercise), the blood sampling (3 times) will be held as mentioned previously. Participants including major eligibility criteria: Twenty four female athletes (aged 20-30 years) will participate in the study. The participants should have no muscular, inflammatory and cardiovascular disease and have not used any dietary or vitamin supplements 8 weeks prior to the study. Main outcome measures (variables): MDA, TAC, SOD and GPx activity, HSP-70 expressing mRNA will be assessed. In addition CK and LDH (indicator of muscular damage), leucocyte count and WBC (indicator of inflammation) and FBS (indicator of glucose intolerance), Hb and Hct (indicator of blood concentration) will be measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016030526909N1**

Registration date: **2016-04-10, 1395/01/22**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-04-10, 1395/01/22

##### Registrant information

###### Name

Sevana Daneghian

###### Name of organization / entity

Ahvaz Jundishapour university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3477 7080

###### Email address

daneghian.s@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2016-09-20, 1395/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of antioxidant rich formula supplementation and aerobic training on glutathione peroxidase and superoxide dismutase activity, determination of HSP-70 expressing mRNA and oxidative stress in female athletes

## Public title

Antioxidants in athletes

## Purpose

Other

## Inclusion/Exclusion criteria

Inclusion criteria: 20-30 years old recreational healthy female athletes; without cardiovascular disease and muscular damage; and have normal blood pressure. Exclusion criteria: Weight loss or any special diet such as vegetarian diet over the past three month; consumption of any sport supplements such as creatine, Amino acids or protein or vitamin and mineral supplements and anti-inflammatory drugs 8 weeks prior the study; having acute and chronic illnesses; high fasting blood sugar or abnormal lipid profile; anemia; hormonal disorders and a BMI less than 18.5 or above 24.9

## Age

From **75 years** old to **65 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **24**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

### 1

#### Registry name

...

#### Secondary trial Id

...

#### Registration date

2017-11-21, 1396/08/30

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Khuzestan, Ahvaz, Ahvaz Jundishapur University of Medical Sciences, Ethics Committee Ahvaz

##### City

Ahvaz

## Postal code

## Approval date

2016-01-23, 1394/11/03

## Ethics committee reference number

IR.AJUMS.REC.1394.617

## Health conditions studied

### 1

#### Description of health condition studied

General health of athletes

#### ICD-10 code

Z10.3

#### ICD-10 code description

Routine general health check-up of sports teams

## Primary outcomes

### 1

#### Description

Total antioxidant capacity (TAC)

#### Timepoint

6 times: 3 times before the intervention (before, 1 hour and 24 hours after exercise test) and 3 times post intervention (before, 1 hour and 24 hours after exercise test)

#### Method of measurement

Specific kit

### 2

#### Description

malondialdehyde (MDA)

#### Timepoint

6 times: 3 times before the intervention (before, 1 hour and 24 hours after exercise test) and 3 times post intervention (before, 1 hour and 24 hours after exercise test)

#### Method of measurement

Specific kit

### 3

#### Description

Super oxide dismutase (SOD) activity

#### Timepoint

6 times: 3 times before the intervention (before, 1 hour and 24 hours after exercise test) and 3 times post intervention (before, 1 hour and 24 hours after exercise test)

#### Method of measurement

Specific kit

### 4

#### Description

Glutathione peroxidase (GPx) activity

#### Timepoint

6 times: 3 times before the intervention (before, 1 hour

and 24 hours after exercise test) and 3 times post intervention (before, 1 hour and 24 hours after exercise test)

**Method of measurement**

Specific kit

**5**

**Description**

HSP-70 expressing mRNA

**Timepoint**

6 times: 3 times before the intervention (before, 1 hour and 24 hours after exercise test) and 3 times post intervention (before, 1 hour and 24 hours after exercise test)

**Method of measurement**

Specific kit

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Antioxidant rich formula made of local materials

**Category**

Other

**2**

**Description**

Semi formula with similar appearance

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

University sport hall

**Full name of responsible person**

Marina Daneghian, PhD candidate of physical education

**Street address**

Pasdaran highway, Islamic Azad University of Tabriz, physical education building

**City**

Tabriz

**2**

**Recruitment center**

**Name of recruitment center**

Tabriz SAMA vocational school

**Full name of responsible person**

Marina Daneghian, PhD candidate of physical education

**Street address**

Elgoli road, stop Khayyam, 35 M Sinai, not far from the towers Tabriz sky

**City**

Tabriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

**Full name of responsible person**

Mostafa Fegghi

**Street address**

Vice chancellor for research, Ahvaz Jundishapour University of Medical Science, Golestan Ave, Ahvaz, Khuzestan Ahvaz

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

**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**

Ahvaz Jundishapour University of Medical Sciences

**Full name of responsible person**

Sevana Daneghian

**Position**

Phd Candidate of Nutrition Science

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## 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*