

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effects aerobic training and resveratrol supplementation on oxidative stress in women with metabolic syndrome

Protocol summary

Study aim

- Comparison of the mean age, weight, height, BMI and blood pressure in each group and between the study groups before and after intervention, and comparison of mean changes between groups
- Comparison of mean serum malondialdehyde in each group and between the study groups before and after intervention, and comparison of mean changes between groups
- Comparison of mean serum total antioxidant capacity in each group and between the study groups before and after intervention, and comparison of mean changes between groups

Design

The present study is a phase 3 clinical trial with control group, parallel groups, double blind and randomized. In this study, 32 female with metabolic based on inclusion criteria and Permuted Block Randomization method randomly using random number table divided to 4 groups included aerobic training group, resveratrol supplement group, aerobic training + resveratrol group and control group.

Settings and conduct

The first group received 3 sessions (60 min) exercise and resveratrol placebo (oral paraffin 400 mg/Day), second group resveratrol 400 mg/day, the third group aerobic exercise + resveratrol, and fourth group resveratrol placebo for 8 weeks. Sampling performed from Mokhaberat club in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being female; Age 18-50 years; Body Mass Index 18.5-29.9; patients with metabolic syndrome; No any other chronic diseases; no taking any drugs or special physical activity. Exclusion criteria: Allergic reaction to resveratrol; pregnancy during the study; any changes in usual diet and life style or intake of multivitamin supplementation; withdrawal of the patient for cooperation.

Intervention groups

- 1) Aerobic training group
- 2) Resveratrol supplement

- group 3) Aerobic training + resveratrol supplement
- group 4) Control group

Main outcome variables

Malondialdehyde serum level
Total anti-oxidant capacity serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042615N1**
Registration date: **2019-02-18, 1397/11/29**
Registration timing: **retrospective**

Last update: **2019-02-18, 1397/11/29**

Update count: **0**

Registration date

2019-02-18, 1397/11/29

Registrant information

Name

Mina Abdolahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3307 3626

Email address

abdolahimina.n@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2018-06-18, 1397/03/28
Actual recruitment end date
 2018-08-13, 1397/05/22
Trial completion date
 2018-08-13, 1397/05/22

Scientific title
 The effects aerobic training and resveratrol supplementation on oxidative stress in women with metabolic syndrome

Public title
 The effect of aerobic training and resveratrol on metabolic syndrome

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Being female Age 18-50 years Body Mass Index 18.5-29.9 Patients with metabolic syndrome No any other chronic diseases No taking any drugs or special physical activity
Exclusion criteria:

Age
 From **18 years** old to **50 years** old

Gender
 Female

Phase
 3

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **32**
 Actual sample size reached: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Patients were divided into 4 groups evenly using Permuted Block Randomization. Then, based on the blocks that were randomly assigned using the random number table, the order of the intervention was determined.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Supplements were coded by a third person and given to participants in a same form package. None of the participants and researchers were aware of the allocation of groups.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Azad University East Tehran Branch

Street address

Bahonar Street, Afsarieh highway

City

Tehran

Province

Tehran

Postal code

۱۸۶۶۱۱۳۱۱۸

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.IAUETB.61009

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E90

ICD-10 code description

Nutritional and metabolic disorders in diseases classified elsewhere

Primary outcomes

1

Description

Malondialdehyde serum levels (pg/dl)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

ELISA method

2

Description

Total Anti-oxidant Capacity serum level (pg/dl)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

ELISA method

Secondary outcomes

1

Description

Weight (kg)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Scales

2**Description**

Height (cm)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Meter strip

3**Description**

Body mass index (weigh/height²)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Calculation based on formula

4**Description**

Waist circumference (cm)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Meter strip

5**Description**

Systolic blood pressure (mmhg)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Manometer

6**Description**

Diastolic blood pressure (mmhg)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Manometer

7**Description**

Fasting blood sugar (mg/dl)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Enzymic

8**Description**

Maximum oxygen ventilation (%)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Bruce test

9**Description**

Triglyceride serum level (mg/dl)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Enzymic

10**Description**

Total cholesterol (mg/dl)

Timepoint

Before the intervention and after 8 weeks of aerobic exercise and resveratrol supplementation

Method of measurement

Enzymic

Intervention groups**1****Description**

The Intervention group 1: Aerobic training, 3 session per week 60 minutes, fore 8 week

Category

Lifestyle

2**Description**

Intervention group 2: Receiving resveratrol supplement 400 mg, in capsule form daily, for 8 week

Category

Prevention

3**Description**

Intervention group 3: Receiving aerobic training, 3 session per week 60 minutes + resveratrol capsule 400 mg daily, fore 8 week

Category

Prevention

4**Description**

Control group: The capsule contain of starch powder 400 mg, daily, for 8 week
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Mokhaberat club
Full name of responsible person
Shima Hadavi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
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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
1
Public or private sector
Private
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
Tehran University of Medical Sciences
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Mina Abdolahi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In addition to data on the main outcome of the study (oxidative stress), the baseline data of participants (such as demographic and anthropometric data) will be shared after blinding.

When the data will become available and for how long

Start the access 6 months after publishing the results

To whom data/document is available

The results of present study will be available to academic researcher and pharmaceutical companies in order to supplement production.

Under which criteria data/document could be used

The data of present study can be used for review, systematic review and meta-analysis articles.

From where data/document is obtainable

Applicants can access to study results through e-mail to a scientist responsible for the study: Dr. Mina Abdolahi
Email: abdolahimina.n@gmail.com

What processes are involved for a request to access data/document

Through sites which the manuscript will be indexed, through research gate site and e-mail to scientist responsible for the study (Dr. Mina Abdolahi)

Comments