Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 perform 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

Malondyaldeid 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

۱۸۶۱۱۳۱۱۸

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

Street address

No. 252, Hafez Street.

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Tehran

Province

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1134845767

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+98 21 6670 5172

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hadavi.nutrition@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Abdolrasoul Daneshjoo

Street address

No. 4, Third twelve metric Ave., Seoul Street.

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Email

phdanesh@yahoo.com

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

Full name of responsible person

Mina Abdolahi

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Mina Abdolahi

Position

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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 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 trough 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 indexed, through research gate site and e-mail to scientist responsible for the study (Dr. Mina Abdolahi)

Comments