

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of aerobic and resistance exercise with and without pomegranate concentrate on lipid profiles and glycemic Indices in inactive obese women with metabolic syndrome

Protocol summary

Study aim

The effect of aerobic-resistance exercise training with and without pomegranate concentrate consumption on some metabolic syndrome indices in obese middle-aged women

Design

Sixty obese women with metabolic syndrome are selected through convenience sampling. Participants are randomly divided into four groups.

Settings and conduct

Sixty obese women with metabolic syndrome are selected through convenience sampling. Participants are randomly divided into four groups according to blood sampling: the first group was aerobic-resistance training without pomegranate concentrate, and the second group was aerobic-resistance training with pomegranate concentrate, the third group is exclusively pomegranate concentrate and the fourth group (without exercise program and consumption of pomegranate concentrate). The planned sports program will be conducted for the first and second groups for 3 months. Participants in the second and third groups will use 50 grams of pomegranate concentrate daily for three months. After the intervention, secondary blood sampling will be obtained to measure lipid profile and glycemic indices.

Participants/Inclusion and exclusion criteria

Obese women with metabolic syndrome Age 35-45 years 32>BMI>27 No training course for at least 2 months prior to the training no affliction with chronic diseases such as cardiovascular, renal disorders, or thyroid disorders consuming no medications

Intervention groups

1: Exercise 2: Exercise with pomegranate concentrate consumption 3: daily consumption of pomegranate concentrate 4: Control

Main outcome variables

Glycemic indices and lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181029041491N1**

Registration date: **2018-11-28, 1397/09/07**

Registration timing: **retrospective**

Last update: **2018-11-28, 1397/09/07**

Update count: **0**

Registration date

2018-11-28, 1397/09/07

Registrant information

Name

Mohammadali Sardar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2178

Email address

sardarma@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2018-09-01, 1397/06/10

Actual recruitment start date

2018-08-01, 1397/05/10

Actual recruitment end date

2018-09-01, 1397/06/10

Trial completion date

2018-12-01, 1397/09/10

Scientific title

The effect of aerobic and resistance exercise with and without pomegranate concentrate on lipid profiles and glycemic Indices in inactive obese women with metabolic syndrome

Public title

Effect of exercise and pomegranate concentrate on metabolic syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

inactive obese women (35-45 age) with metabolic syndrome $BMI > 27$ no training course for at least 2 months prior to the training no affliction with chronic diseases such as cardiovascular, renal disorders, or thyroid disorders no menopause non-smokers consuming no medications

Exclusion criteria:

Unwillingness to continue the study the disease that requires special treatments Severe change in diet

Age

From **35 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign randomness to the first one, it is poured into a repository code A, B, C, and D, and for the first one a picking code is removed, and then the research unit is assigned in one of the following groups, respectively To find Group 1: Aerobic- Resistance Exercise Second group: Aerobic - Resistant Exercise Concentrate with Pomegranate Group 3: daily consumption of pomegranate concentrate Group 4: Control (no exercise and no pomegranate concentrate)

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Azadi Square, Paradise Daneshgah, School of Medicine

City

Mashhad

Province

Razavi Khorasan

Postal code

91779-48564

Approval date

2018-07-25, 1397/05/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.064

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

fasting blood sugar

Timepoint

24 hours prior to the protocol and 48 hours after the last protocol session

Method of measurement

Blood sampling

2

Description

fasting insulin

Timepoint

24 hours prior to the protocol and 48 hours after the last protocol session

Method of measurement

Blood sampling

3

Description

glycosylated hemoglobin

Timepoint

24 hours prior to the protocol and 48 hours after the last protocol session

Method of measurement

Blood sampling

4

Description

C-peptide

Timepoint

24 hours prior to the protocol and 48 hours after the last protocol session

Method of measurement

Blood sampling

5

Description

cholesterol

Timepoint

24 hours prior to the protocol and 48 hours after the last protocol session

Method of measurement

Blood sampling

6

Description

TG

Timepoint

24 hours prior to the protocol and 48 hours after the last protocol session

Method of measurement

Blood sampling

7

Description

HDL

Timepoint

24 hours prior to the protocol and 48 hours after the last protocol session

Method of measurement

Blood sampling

8

Description

LDL

Timepoint

24 hours prior to the protocol and 48 hours after the last protocol session

Method of measurement

Blood sampling

9

Description

Insulin Resistance

Timepoint

24 hours prior to the protocol and 48 hours after the last protocol session

Method of measurement

homeostasis model assessment (HOMA-IR) formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: consume a daily amount of pomegranate concentrate (50 g) in two meals of 25 g after lunch and dinner

Category

Prevention

2

Description

Intervention group: combination of aerobic and resistance exercises for 3 month

Category

Prevention

3

Description

Intervention group: combination of aerobic and resistance exercises for 3 month with consume a daily amount of pomegranate concentrate

Category

Prevention

4

Description

Control group: No exercise; No pomegranate concentrate consumption

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Ali Sardar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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tafaghodim@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

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**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammadali Sardar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main implications

When the data will become available and for how

long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

To repeat the research / use the results of the research in review studies

From where data/document is obtainable

Corresponding Author: Mohammad Ali Sardar
sardarma@mums.ac.ir

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

Up to one month after receiving the email from the applicant, the paper file published by the author is sent to him

Comments