Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of eight weeks of aerobic training with and without green coffee consumption on lymphocyte ABCG1 Gene Expression, Apo-B100 and some of the Cardiovascular risk factor in 30 non-Athlete and overweight women

Protocol summary

Study aim

The effect of eight weeks of aerobic training and green coffee consumption on ABCG1, Apo-B100 gene expression and some cardiovascular risk factors in overweight non-athletic women.

Design

A randomized, single-blind, placebo-controlled clinical trial

Settings and conduct

During the call at the Shahid Beheshti Club in Mashhad, 30 participants were randomly selected and randomly divided into two groups of green coffee consumption and placebo consumption And they were told that all the capsules were green coffee.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 35 to 45 years with overweight and BMI ranging from 25 to 29.9 kg / m2 and not trained. Be physically and mentally healthy and not at all menopausal. During the three days before and after the menstrual cycle, they took no medication at all. They have not used dietary, nutritional, and dietary supplements since two months ago. Do not have a special diet. They did not smoke, and were also obliged to attend meetings and observe conditions set by researchers and educators from beginning to end.
Exclusion criteria: Non-compliance, Going on a trip, Non-compliance with diet and Illness and absence at training sessions

Intervention groups

Exercise group with green coffee intake: start aerobic exercise at 40% intensity (maximum heart rate) / 30 min / three sessions per week and increase to 60 min / 70% intensity / three sessions per week. Aerobic exercise group with placebo: similar to group 1

Main outcome variables

ABCG1 gene; ApoB100; HDL; LDL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191227045907N1**
Registration date: **2020-01-22, 1398/11/02**
Registration timing: **retrospective**

Last update: **2020-01-22, 1398/11/02**
Update count: **0**

Registration date

2020-01-22, 1398/11/02

Registrant information

Name

Ahmad Shajiee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3833 6796

Email address

ahmad.shajie@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2018-12-31, 1397/10/10

Trial completion date

2020-03-05, 1398/12/15

Scientific title
Effect of eight weeks of aerobic training with and without green coffee consumption on lymphocyte ABCG1 Gene Expression, Apo-B100 and some of the Cardiovascular risk factor in 30 non-Athlete and overweight women

Public title
Effect of aerobic training and green coffee consumption in overweight women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
BMI range between 25 and 29.9 kg / m2 non-athlete Have physical and mental health No disease Do not be menopausal Be in the three days before and after menstruation Do not take any medication They have not used nutritional and nutritional supplements since two months ago Do not have a special diet No smoking If they wish to participate in the research, they are obliged to comply with the conditions set forth from beginning to end. Age range between 35-45 years
Exclusion criteria:
Non-compliance Disease Having a diet taking medication Being in the menstrual cycle Taking nutritional supplements Go to travel
Age
From **35 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Note the total names of participants on paper in a container, then randomly withdrawing 30 individuals as sample size from the container containing the names, and then randomly divided into two groups of 15 individuals each with aerobic exercise with and without green coffee.
Blinding (investigator's opinion)
Single blinded
Blinding description
The green coffee capsules were given to the exercise group with the green coffee and the placebo capsules containing wheat flour to the placebo exercise group. The capsules were similar in appearance, odor, color and taste, and only the subjects were not aware of the contents of the capsules.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad University of Neyshabour Branch
Street address
Islamic Azad University, Neyshabur Branch, Imam Mohammad Ghazali Boulevard, Neyshabur
City
MASHHAD
Province
Razavi Khorasan
Postal code
۹۳۱۹۷۹۷۱۳۹
Approval date
2018-12-13, 1397/09/22
Ethics committee reference number
IR.IAU.NEYSHABUR.REC.1397.018

Health conditions studied

1

Description of health condition studied
ABCG1 gene
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
ATP-binding cassette Transport G1 gen
Timepoint
48 hours before and 48 hours after the first and last aerobic training session
Method of measurement
Centrifuge and isolate lymphocytes and then investigate gene expression by RT-PCR method

2

Description
Apolipoprotein B100
Timepoint
48 hours before and 48 hours after the first and last aerobic training session
Method of measurement
5 cc of blood sample and ELISA method

3

Description
High-density lipoprotein
Timepoint

48 hours before and 48 hours after the first and last aerobic training session

Method of measurement

Spectrophotometry method

4

Description

Low-density lipoprotein

Timepoint

48 hours before and 48 hours after the first and last aerobic training session

Method of measurement

Spectrophotometry method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aerobic exercise with green coffee intake: 40-70% MHR / three sessions per week / 30-60 minutes per session. 400 mg capsules daily one hour before exercise

Category

Prevention

2

Description

Intervention group: Aerobic exercise with green coffee intake: 40-70% MHR / three sessions per week / 30-60 minutes per session. placebo capsules daily one hour before exercise

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Martyr Beheshti Club of Mashhad

Full name of responsible person

Ahmad Shajie

Street address

Mashhad Ferdowsi Boulevard Shahid Beheshti Club

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ahmad Zendedel

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Neyshabour, Research Street, Islamic Azad University, Neyshabour Branch Complex

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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

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

Ferdowsi University of Mashhad

Full name of responsible person

Amir Rashidlamir

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport physiology

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Person responsible for scientific inquiries

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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
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
The effect of eight weeks of aerobic exercise and green coffee consumption on ABCG1 lymphocyte, Apo-B100 gene expression and LDL / HDL and CT / HDL ratio in overweight non-athletic women
When the data will become available and for how long
Two months after printing the results
To whom data/document is available
Researchers and anyone you know in the field of science
Under which criteria data/document could be used
Protecting Data Security - Use in scientific and research areas
From where data/document is obtainable
Amir Rashidlamir- 09151514174- Ferdowsi University of Mashhad School of Sport Sciences - amir.rashidlamir@gmail.com Ahmad Shajie- 09155048659- Neyshabour Azad University School of Sport Sciences- ahmad.shajie@gmail.com
What processes are involved for a request to access data/document
Two Months After Publishing in Scientific Research Journals
Comments
Thanks for your kindness