

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The Effect of 6 Weeks Caffeine Supplementation with Aerobic Exercise on Central Body Fat in Overweight Women.

Protocol summary

Study aim

This study is a clinical trial. The objective of this study is to investigate the effect of moderate aerobic exercise with caffeine supplementation on central body fat reduction. Thirty women with body mass index ≥ 25 and $30 >$, who do not have diseases that affecting physical activity, heart rate or nutrition status will be recruited.

Design

A randomised trial with a control group, superiority, parallel group trial with blinded participants and outcome assessor.

Settings and conduct

The trial will be run in the Emam Khomeini Hospital. Aerobic exercise in moderate intensity will be prescribed according to results of treadmill test and heart rate calculation. The participants will be requested to do 30-minutes aerobic exercise including brisk walking or running on treadmill 3-5 days per week for 6 weeks. Body composition, waist circumference, abdominal and supra-iliac skin folds will be measured and compared before and after the intervention. The participants and outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female sex; without pregnancy or regular physical activity or cigarette smoking; without any diseases that affect the heart rate, diet or physical activity; without significant weight reduction over the past 6 months Exclusion criteria: Pregnancy during the trial; refuse participation in the trial

Intervention groups

All of the participants will receive caffeine (100 mg) or placebo tablets two times per day, for 6 weeks. All of the subjects will be requested to do aerobic exercise 30 min, 3 to 5 days per week.

Main outcome variables

Waist circumference; abdominal and supra-iliac skin fold; body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111025007903N11**

Registration date: **2019-03-06, 1397/12/15**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-06, 1397/12/15**

Update count: **0**

Registration date

2019-03-06, 1397/12/15

Registrant information

Name

Zahra Alizadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2282

Email address

z_alizadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of 6 Weeks Caffeine Supplementation with Aerobic Exercise on Central Body Fat in Overweight Women.

Public title

Caffeine and central fat reduction

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Female sex Without pregnancy or regular physical activity or cigarette smoking Without any diseases that affect the heart rate, diet or physical activity Without significant weight reduction over the past 6 months

Exclusion criteria:

Pregnancy during trial Refuse participation in the trial

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

We use simple randomization. Each person takes her own number. Each number is allocated in the control or intervention group according to a table of random numbers. The allocation concealment will be done by the third person who does not contribute to the other process of the trial.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, investigator and data analyser will be blind. A co-worker who not participate in the other trial sections will deliver the caffeine tablets or placebo to the participants according to a randomization table.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Tehran University of Medical Sciences

Street address

The Center of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.314

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Central fat reduction

Timepoint

Baseline and 6 weeks later

Method of measurement

Waist circumference and local skin fold measurement

Secondary outcomes

1

Description

Body composition

Timepoint

Baseline and 6 weeks later

Method of measurement

Body analyzer device (4Compartment body composition analyzer AVIS33)

Intervention groups

1

Description

Intervention group: The intervention group uses 100 mg caffeine tablets (API production.co) 2 times per day (morning and evening). They do aerobic exercise including brisk walking or running on the treadmill, 3-5 days per week for 6 weeks.

Category

Prevention

2

Description

Control group: The control group uses placebo tablets (Exir production.co), 2 times per day (morning and evening). They do aerobic exercise including brisk walking or running on the treadmill, 3-5 days per week for 6 weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Zahra Alizadeh

Street address

Imam Khomeini Hospita, Blvd. Keshavarz, Square Vliasr

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hajar Moammaee

Street address

4th Floor, The Center of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Alizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Primary outcomes and others according to researchers request

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Please contact with this e-mail: z_alizadeh@tums.ac.ir

Under which criteria data/document could be used

Please contact with this e-mail: z_alizadeh@tums.ac.ir

From where data/document is obtainable

Please contact with this e-mail: z_alizadeh@tums.ac.ir

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

Please contact with this e-mail: z_alizadeh@tums.ac.ir

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Alizadeh

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Latest degree

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