Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Effect of green tea extract and endurance training on inflammatory markers, adiponectin and irisin level

Protocol summary

Study aim

The aim of this study is to investigate the effects of green tea extract supplementation on exercise induced changes in body composition, irisin, adipokines and pro-inflammatory cytokines in inactive overweight men and women.

Design

Study design: Randomized double-blinded controlled clinical trial. Blinding is carried out for subjects and researchers and randomization will done using quadratic block. Statistical software (Minitab) will use to perform randomized block. Population and sample size: 75 overweight sedentary men and women who are not participated in any regular training program for at least 6 months before the study.

Settings and conduct

75 overweight sedentary men and women who are eligible and are referred to a sport medicine clinic affiliated to Ferdowsi University of Mashhad, Mashhad, Iran will be selected. Blinding is carried out for subjects and researchers and randomization will done using quadratic block. Statistical software (Minitab) will use to perform randomized block.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Overweight men and women aged 30 to 50 years without participating in any regular training program Exclusion criteria: People with obesity, recent infections, joint and bone injuries, and symptoms of metabolic disease.

Intervention groups

Intervention 1: received one 500 mg green tea extract capsule, 1 hour before each exercise training session, for wight weeks Intervention 2: exercise training including aerobics, circuit training, and fast walking or jogging, 3 times/wk with a moderate intensity Intervention 3: received one capsule containing chickpea flour, for wight weeks

Main outcome variables

Body fat, irisin; interleukin-6; adiponectin; tumor necrosis factor-alpha; C-reactive protein; dietary intake

General information

Reason for update

Editing the name of ethic committee

Acronym

IRCT registration information

IRCT registration number: **IRCT20151025024699N3**
Registration date: **2019-08-05, 1398/05/14**
Registration timing: **retrospective**

Last update: **2021-02-12, 1399/11/24**
Update count: **1**

Registration date

2019-08-05, 1398/05/14

Registrant information

Name

Damoon Ashtary-Larky

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 614436106

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-07-05, 1397/04/14

Actual recruitment start date

2018-04-03, 1397/01/14

Actual recruitment end date

2018-09-05, 1397/06/14

Trial completion date

2018-11-21, 1397/08/30

Scientific title

Effect of green tea extract and endurance training on inflammatory markers, adiponectin and irisin level

Public title

Effect of green tea extract and endurance training on inflammation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 30-50 BMI=25-30 Don’t taking the glucose and lipid- lowering drugs Interesting in participation in research Without any metabolic disease No smoking No alcoholism Not taking supplements (including vitamins, minerals, ergogenic aids) and medication for at least 2 months before the study Not participating in any regular training program for at least 6 months before the study

Exclusion criteria:

Use of immune system suppressor drugs 6 mounts before research Women with polycystic ovary syndrome Obesity (BMI ≥ 30 kg/m2) No interesting for participation Recent infections Joint and bone injuries Metabolic disease

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will done using quadratic block. Statistical software (Minitab) will use to perform randomized block.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study design: Parallel double-blind (both patients and researchers) clinical trial.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Islamic Azad University of Neyshabur, Neyshabur, Iran

Street address

Pazhuhesh Blvd, Neyshabur

City

Neyshabur

Province

Razavi Khorasan

Postal code

9319975853

Approval date

2018-04-09, 1397/01/20

Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1397.010

Health conditions studied

1

Description of health condition studied

Healthy, overweight

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Irisin

Timepoint

Before and two weeks after intervention

Method of measurement

ELISA

2

Description

Interleukin 6

Timepoint

Before and two weeks after intervention

Method of measurement

ELISA

3

Description

Tumor necrosis factor alpha

Timepoint

Before and two weeks after intervention

Method of measurement

ELISA

4

Description

Adiponectin

Timepoint

Before and two weeks after intervention

Method of measurement

ELISA

5

Description

C-reactive protein

Timepoint

Before and two weeks after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Body fat

Timepoint

Before and two weeks after intervention

Method of measurement

Body fat Analyzer

2

Description

Dietary intake

Timepoint

Before and two weeks after intervention

Method of measurement

Food record questionnaire

Intervention groups

1

Description

Intervention group: received one 500 mg green tea extract capsule, 1 hour before each exercise training session, for eight weeks

Category

Prevention

2

Description

Intervention group: exercise training including aerobics, circuit training, and fast walking or jogging, 3 times/wk with a moderate intensity, for eight weeks

Category

Lifestyle

3

Description

Control group: received one capsule containing chickpea flour, for eight weeks

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Vice chancellor for Research, Ferdowsi University of Mashhad

Full name of responsible person

Dr. Amir Rashidlamir

Street address

Physical education faculty, Ferdowsi University of Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Ferdowsi University of Mashhad, Iran.

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

Vice chancellor for Research, Ferdowsi University of Mashhad, Iran.

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

Ferdowsi University of Mashhad

Full name of responsible person

Reza Bagheri

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Physiology

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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

itle and more details about the data/document

Publication of protocol study in form of the article and also data publication in the original article. The total potential data can be shared after unidentifiable subjects.

When the data will become available and for how long

6 months after the publication of results

To whom data/document is available

All researchers who have access to clinical trials databases

Under which criteria data/document could be used

The only way for using the data is after the publication of the article in the indexed ISI journal.

From where data/document is obtainable

Via database websites such as PubMed and google scholar and via email address: damoon_ashtary@yahoo.com

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

The original article reaches the requestor by email within a maximum of one week.

Comments