

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The short-term effect of caffeine supplement on changes in myocardial oxygen consumption, heart rate variability, Delayed-Onset Muscle Soreness (DOMS) and rating of perceived exertion in trained young men

Protocol summary

Study aim

The short-term effect of caffeine supplement on changes in myocardial oxygen consumption, heart rate variability, Delayed-Onset Muscle Soreness (DOMS) and rating of perceived exertion in trained young men

Design

A phase 3 randomized with G power software , crossover, single-blind clinical trial was conducted on 12 trained young men.

Settings and conduct

It was done at Gilan University after 8 hours of fasting and sharing breakfast with the same calories and 320 calories. Blinding was performed using tablets and placebo in the supplement and placebo groups.

Participants/Inclusion and exclusion criteria

Young trained men with a history of at least 6 months of regular training with a homogeneous age and weight range 2) Lack of sensitivity and lack of medical contraindications for consuming caffeine and lack of medical contraindications for sports activities 3) No long-term history of caffeine consumption 4) having physical health and no injuries and without special clinical considerations 2) Observation of hypersensitivity to caffeine consumption in the subject (insomnia, restlessness, behavioral changes, irritability and increased heart rate)

Intervention groups

Caffeine supplementation and circuit resistance training
Placebo and circuit resistance training

Main outcome variables

Used for coaches and preventing overtraining of athletes, preventing damage to the cardiovascular system and sudden death

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240521061865N1**

Registration date: **2024-06-17, 1403/03/28**

Registration timing: **retrospective**

Last update: **2024-06-17, 1403/03/28**

Update count: **0**

Registration date

2024-06-17, 1403/03/28

Registrant information

Name

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Name of organization / entity

Guilan university

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-19, 1403/01/31

Expected recruitment end date

2024-05-14, 1403/02/25

Actual recruitment start date

2024-04-19, 1403/01/31

Actual recruitment end date

2024-05-14, 1403/02/25

Trial completion date

2024-05-14, 1403/02/25

Scientific title

The short-term effect of caffeine supplement on changes in myocardial oxygen consumption, heart rate variability, Delayed-Onset Muscle Soreness (DOMS) and rating of perceived exertion in trained young men	
Public title	The short-term effect of caffeine supplement on changes in myocardial oxygen consumption, heart rate variability, Delayed-Onset Muscle Soreness (DOMS) and rating of perceived exertion in trained young men
Purpose	Health service research
Inclusion/Exclusion criteria	Inclusion criteria: 1) young trained men with at least 6 months of regular training with ahomogeneous age and weight range 2) no reduction and no medical prohibition in caffeine consumption and no medical prohibition to perform sports activities 3) no long-term history of caffeine consumption 4) physically healthy and no injuries and no special clinical considerations Exclusion criteria: Observing excessive consumption of caffeine in the subject (insomnia, restlessness, behavioral changes, mobility and increased heart rate)
Age	From 20 years old to 30 years old
Gender	Male
Phase	3
Groups that have been masked	Participant
Sample size	Target sample size: 12 More than 1 sample in each individual Number of samples in each individual: 2 SUPPLEMENT and PLACEBO Actual sample size reached: 12
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Single blinded
Blinding description	participants, contributors. Lack of knowledge about taking pills or placebo
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	<u>1</u> Ethics committee Name of ethics committee University of Guilan Street address Qazvin-Rasht road City Rasht Province Guilan Postal code 4199613776 Approval date 2024-05-18, 1403/02/29 Ethics committee reference number IR.GUILAN.REC.1403.048
Health conditions studied	<u>1</u> Description of health condition studied Effects of caffeine supplementation on cardiac rhythm changes in trained and healthy young men with circuit resistance training ICD-10 code ICD-10 code description
Primary outcomes	<u>1</u> Description Heart rhythm song of healthy and trained young men Timepoint Variability of heart rate, blood pressure and perception of baseline and post-exercise pressure, delayed concussion up to 72 hours after exercise Method of measurement Cubius and Elite HRV software, sphygmomanometer, Borg scale, McGill questionnaire
Secondary outcomes	empty
Intervention groups	<u>1</u> Description Intervention group: 1They ingested caffeine Alhavi Enercaff 200 Capsules made in Iran (4mg/kg) After 8 hours of fasting consumption, participants were monitored throughout a 30minutes ingested period, then complete resistance training with an intensity of 70-80% 1RM, followed by 30 minutes of recovery. Heart rate variability indexes (RMSSD and LF,HF, LF/HF) were taken with Elite HRV and Kubios Software at the baseline, 30 minutes after caffeine ingestion, recovery 1 (0-5 minutes), recovery 2 (5-10)recovery3(15-20 minutes),

recovery 4(25-30)pressure product (RPP) were taken at the baseline, pre training and post training minutes after caffeine consumption, immediately after exercise 30 minutes of recovery period , rating of perceived exertion (RPE) immediately , 2min, 3min, 5min and 10 minutes of recovery period with Borg scale delayed onset muscle soreness were taken though ROM test, MVC test from Thigh and knee extensor sergeant test and McGill questionnaire for 72 hours after RT.

Category

Prevention

2

Description

Intervention group: 2 Intervention group: 1 They ingested placebo tablet Contains elderberry powder (4mg/kg) After 8 hours of fasting consumption, participants were monitored throughout a 30 minutes ingested period, then complete resistance training with an intensity of 70-80% 1RM, followed by 30 minutes of recovery. Heart rate variability indexes (RMSSD and LF, HF, LF/HF) were taken with Elite HRV and Kubios Software at the baseline, 30 minutes after caffeine ingestion, recovery 1 (0-5 minutes), recovery 2 (5-10) recovery 3 (15-20 minutes), recovery 4 (25-30) pressure product (RPP) were taken at the baseline, pre training and post training minutes after caffeine consumption, immediately after exercise 30 minutes of recovery period , rating of perceived exertion (RPE) immediately , 2min, 3min, 5min and 10 minutes of recovery period with Borg scale delayed onset muscle soreness were taken though ROM test, MVC test from Thigh and knee extensor sergeant test and McGill questionnaire for 72 hours after RT.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan university

Full name of responsible person

Arsalan Damirchi

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Sponsors / Funding sources

1

Sponsor

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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

The University of Guilan

Proportion provided by this source

100

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

The University of Guilan

Full name of responsible person

Ronak latifnezhad

Position

Msc student

Latest degree

Master

Other areas of specialty/work

Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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

Person responsible for updating data

Contact

Name of organization / entity

The University of Guilan

Full name of responsible person

Ronak latifnezhad

Position

Msc student

Latest degree

Master