Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Ronak Latifnezhad

Name of organization / entity
Guilan university

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Iran (Islamic Republic of)

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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

1

Ethics committee

Name of ethics committee

University of Guilan

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Qazvin-Rasht road

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Guilan

Postal code

4199613776

Approval date

2024-05-18, 1403/02/29

Ethics committee reference number

IR.GUILAN.REC.1403.048

Health conditions studied

1

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

1

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

1

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 exercis30 minutes of recovery period , rating of perceived exertion (RPE) immediately ,2min,3min,5min and10 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 for72hours after RT.

Category

Prevention

2

Description

Intervention group: 2Intervention group: 1They ingested placebo tablet Contains elderberry powder (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 exercis30 minutes of recovery period , rating of perceived exertion (RPE) immediately ,2min,3min,5min and10 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 for72hours after RT.

Category

Prevention

Recruitment centers

1

Recruitment center

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Guilan university
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Sponsors / Funding sources

1

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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

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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