

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Ronak Latifnezhad

##### Name of organization / entity

Guilan university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 918 478 8697

##### Email address

royaaalootfi@gmail.com

##### 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

#### 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

## 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

##### Name of recruitment center

Guilan university

##### Full name of responsible person

Arsalan Damirchi

##### Street address

Qazvin-Rasht road

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##### Province

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##### Phone

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The University of Guilan

##### 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

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 ofGuilan

##### Full name of responsible person

Ronak latifnezhad

##### Position

Msc student

##### Latest degree

Master

##### Other areas of specialty/work

Physiology

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## Person responsible for scientific inquiries

### Contact

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Professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Other areas of specialty/work**

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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