

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of caffeine dose on heart rate variability, rate pressure product and some fatigue indexes after endurance exercise in trained men

Protocol summary

Study aim

Caffeine increases the activity of the sympathetic nervous system in healthy people, changes in the nervous system can be assessed using heart rate variability. The aim of this study was to evaluate the effect of caffeine dose on the recovery of some indicators of the autonomic nervous system after endurance activity.

Design

Subjects were referred to the laboratory in 3 separate sessions with an interval of at least 3 and a maximum of 6 days of wash-out. In the laboratory, after 15 minutes in a sitting position, HR, SBP, DBP, and HRV were measured and after eating the same breakfast containing 540 kcal capsules containing doses of 6 and 9 mg/kg body weight of caffeine or placebo. They received 300 ml of water with the single-blind method.

Settings and conduct

Exercise Physiology Laboratory, Faculty of Physical Education and Sports Sciences, Guilan University. After supplementation to maximize caffeine concentration in the blood, subjects were seated for 35 minutes. Immediately after that, they started running on a treadmill for 12 minutes, equivalent to 75% of the maximum oxygen consumption. After the activity, there was a 60-minute recovery phase in which HRV levels were recorded at 10-minute intervals.

Participants/Inclusion and exclusion criteria

Men trained with VO₂max at least 50 with a history of at least 2 years of regular exercise, with good body composition, no history of acute and chronic diseases, no history of smoking, no cardiovascular problems, no anabolic steroids or central nervous system stimulant And other sports supplements in the last 6 months

Intervention groups

Caffeine dose groups of 6 and 9 mg/kg body weight

Main outcome variables

Parameters related to heart rate variability (RMSSD and LF/HF), systolic and diastolic blood pressure, myocardial

oxygen cost, RPP, pain sensation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190720044283N4**

Registration date: **2021-10-27, 1400/08/05**

Registration timing: **retrospective**

Last update: **2021-10-27, 1400/08/05**

Update count: **0**

Registration date

2021-10-27, 1400/08/05

Registrant information

Name

Siamand Abdollahpour

Name of organization / entity

Guilan university of medical sciences

Country

Iran (Islamic Republic of)

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+98 13 3369 0274

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-26, 1400/07/04

Expected recruitment end date

2021-10-27, 1400/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of caffeine dose on heart rate variability, rate pressure product and some fatigue indexes after endurance exercise in trained men

Public title

Caffeine Dose and Autonomic Recovery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects have exercised regularly (three sessions per week or more) over the past two years None of the subjects used supplements or ergogenic aids. No use of anabolic steroids or central nervous system stimulants in the last two years No caffeine intake of more than 300 mg per day No history of cardiovascular and metabolic diseases No history of alcohol and tobacco use Optimal body composition and physical health

Exclusion criteria:

Age

From **18 years** old to **22 years** old

Gender

Male

Phase

N/A

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: **3**

The control group, the low-dose intervention group and the high-dose intervention group

Randomization (investigator's opinion)

Randomized

Randomization description

Use the random selection method by Excel software. In this method, we first enter the names of the subjects in Excel, and then in another part, we specify the position of the desired groups in two separate sections of 6 subjects. Then in these two sections, we will execute the following code so that people are randomly placed in groups of 6 subjects.

```
=INDEX($A$3:$A$12,RANDBETWEEN(1,ROWS($A$3:$A$12)),1)
```

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, subjects were not aware of how caffeine or placebo was distributed. The determined amount of supplement and placebo was weighed for each subject separately and was delivered to the subjects by coding by the laboratory operator on each day of the test.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Sports Science Institute (SSRI)

Street address

Fifth Alley, Mir Emad St., Ostad Motahhari St.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2021-09-15, 1400/06/24

Ethics committee reference number

IR.SSRI.REC.1400.1230

Health conditions studied

1

Description of health condition studied

Recovery of indicators of the autonomic nervous system

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart rate variability

Timepoint

15 minutes after attending the laboratory (before breakfast), 35 minutes after supplementation, immediately and at 1, 2, 3, 5, 10, 20, 40, and 60 minutes after exercise

Method of measurement

Heart rate monitor (Polar-H10)

2

Description

Systolic and diastolic blood pressure

Timepoint

15 minutes after attending the laboratory (before breakfast), 35 minutes after supplementation, immediately and at 1, 2, 3, 5, 10, 20, 40, and 60 minutes after exercise

Method of measurement

hand barometer (Zenith, ZTH-5001, Switzerland)

3

Description

Rate pressure product

Timepoint

At all points when heart rate and blood pressure will also be measured.

Method of measurement

It is calculated by multiplying systolic blood pressure and heart rate.

4

Description

Rate of Perceived Exertion (RPE)

Timepoint

Immediately after exercise

Method of measurement

Borg scale (6-20)

5

Description

Muscle Pain

Timepoint

Immediately after exercise until one hour after exercise

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dose of 6 mg/kg of caffeine and endurance activity

Category

N/A

2

Description

Intervention group: Dose of 9 mg/kg of caffeine and endurance activity

Category

N/A

3

Description

Control group: Taking placebo along with performing endurance activity

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Physical Education and Sports Sciences

Full name of responsible person

Dr. Javad Mehrabani

Street address

5th Kilometer of Persian Gulf Highway, Rasht, Guilan Province, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

University of Guilan

Proportion provided by this source

1

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

Faculty of Physical Education and Sports Sciences,
University of Guilan

Full name of responsible person

Dr. Javad Mehrabani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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Latest degree

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Other areas of specialty/work

Exercise physiology

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Person responsible for updating data

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Other areas of specialty/work

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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

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

Title and more details about the data/document

After analyzing the data, only part of the data related to
the main outcome will be shared.

When the data will become available and for how long

After approval by the journal publishing the study report

To whom data/document is available

Journal publisher of study reports

Under which criteria data/document could be used

By getting permission from the journal publish the study
report

From where data/document is obtainable

Journal publisher of study reports

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

Public and private terms Journal of the study report

Comments