

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of downhill running and short-term caffeine supplementation on some of delayed onset muscle soreness indices in male non-athletes

Protocol summary

Summary

Introduction: In accordance with some conflict results about the effect of acute and long-term caffeine supplementation on exercise-induced muscle soreness, this study will conduct to determine the effect of short-term caffeine supplementation on some indicators of delayed onset muscle soreness (DOMS) in male non-athletes after one bout downhill running protocol.

Methods: Twenty male untrained men (aged 22-28 year, BMI 18-22, and VO₂max 45-50 ml/kg/min) in a quasi-experimental, randomized and double-blind design will allocate equally into supplement and placebo groups (5mg/kg/day caffeine or dextrose intake). After 14-day supplementation period, all subjects will participate in one bout downhill running protocol on a treadmill (-15% incline) for 30 minutes with 65% heart rate reserve (HRR). Biochemical (Serum creatine kinase: CK), inflammatory (Peripheral blood leukocyte count; Serum C-reactive protein: CRP; Thigh circumference and perceived soreness) and performance indicators (Flexibility, maximal isometric strength and explosive power lower limb) will determine in both groups during four phases (baseline, after the supplement period, immediately and 24 hours after the exercise). Serum CK and CRP will measure by photometric and immunoturbidometric assays (with commercial Pars-Azmoon kits), respectively. The peripheral blood leukocytes counts will determine by automatic analyzer. Muscle circumference and perceived soreness will determine by flexible tap and Talag Scale, respectively. Flexibility, maximal isometric strength and explosive power of lower limb will determine by wells, dynamometric and sargent vertical jump tests, respectively. Data will be expressed as mean (\pm SD) and analyzed by repeated measure ANOVA, Bonferroni and independent t test at $\alpha \leq 0.05$.

General information

Acronym

Caf2010Nikkhread

IRCT registration information

IRCT registration number: **IRCT201203104663N8**

Registration date: **2012-08-04, 1391/05/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-04, 1391/05/14

Registrant information

Name

Afshar Jafari

Name of organization / entity

University of Tabriz

Country

Iran (Islamic Republic of)

Phone

+98 41 1339 3251

Email address

ajafari@tabrizu.ac.ir

Recruitment status

Recruitment complete

Funding source

The Research will funded by Graduate office in University of Tabriz.

Expected recruitment start date

2010-05-15, 1389/02/25

Expected recruitment end date

2010-06-15, 1389/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

8930

Scientific title

Effect of downhill running and short-term caffeine supplementation on some of delayed onset muscle soreness indices in male non-athletes

Public title

Caffeine effect on exercise-induced damages in non-athletes

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: Healthy males; non-athletes; aged 22-28 years; BMI 18-22 Kg/m²; aerobic power 45-50 ml/kg/min; without any anti-inflammatory and medical drugs such as caffeine > 100 mg/day (during 6 months prior to the study). Exclusion criteria: chronic diseases; injuries; and uncontrolled intake of oxidative supplements; uncontrolled intake of anti-inflammatory drugs and stimulants (during the period).

Age

From **22 years** old to **28 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht St. Daneshgah St. Tabriz

City

Tabriz

Postal code

Approval date

2010-08-24, 1389/06/02

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Downhill running-induced muscle damage

ICD-10 code

M79.1

ICD-10 code description

Myalgia

Primary outcomes

1

Description

Total Serum Creatine kinase (CK)

Timepoint

Before and after 14-day supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

Photometric methods with commercial kits (Pars-Azmoon)

2

Description

C-reactive protein

Timepoint

Before and after 14-day supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

immunospectrometric assay

3

Description

Peripheral blood leukocyte count

Timepoint

Before and after 14-day supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

It will determine by automatic analyzer.

4

Description

Perceived soreness

Timepoint

Before and after 14-day supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

Talag Scale

5

Description

Muscle circumference

Timepoint

Before and after 14-day supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

It will determine by flexible tap

6

Description

Lower limb flexibility

Timepoint

Before and after 14-day supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

Sit and reach test (wells)

7

Description

Lower limb maximal isometric strength

Timepoint

Before and after 14-day supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

Dynamometric measurement

8

Description

Lower limb power

Timepoint

Before and after 14-day supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

Sargent vertical jump test

Secondary outcomes

1

Description

Maximal Oxygen Consumption

Timepoint

10 day before supplementation

Method of measurement

It will determine with Bruce treadmill Test.

2

Description

Body composition

Timepoint

10 day before supplementation

Method of measurement

It will determine with Skin-fold test (caliper and ACSM's

Formula).

3

Description

Rating perceived exertion

Timepoint

It will determine at immediately before and after each bout of the exercises.

Method of measurement

It will determine by Borg Scale.

Intervention groups

1

Description

Each participant will receive dextrose (5 mg/kg body weight/day) for fourteen consecutive days. After the supplementation period, all subjects will participate in one bout downhill running protocol on a treadmill (-15% incline) for 30 minutes with 65% heart rate reserve (HRR).

Category

Placebo

2

Description

Each participant will receive caffeine (5 mg/kg body weight/day) for fourteen consecutive days. After the supplementation period, all subjects will participate in one bout downhill running protocol on a treadmill (-15% incline) for 30 minutes with 65% heart rate reserve (HRR).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Tabriz

Full name of responsible person

Dr Afshar Jafari

Street address

Faculty of physical education & sports sciences, University of Tabriz, Tabriz, Iran.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Graduate office in University of Tabriz

Full name of responsible person

Dr Hamidreza Ghassemzadeh

Street address

University of Tabriz, 29 Bahman Ave, Tabriz, Iran.

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Graduate office in University of Tabriz

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Person responsible for scientific inquiries****Contact****Name of organization / entity**

University of Tabriz

Full name of responsible person

Dr Afshar Jafari

Position

Associate Professor (PhD) in Molecular Exercise Physiology

Other areas of specialty/work**Street address**

Faculty of physical education & sports sciences, University of Tabriz, Tabriz, Iran.

City

Tabriz

Postal code**Phone**

+98 41 1339 3251

Fax

+98 41 1335 6008

Email

ajafari@tabrizu.ac.ir

Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty