

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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 VO<sub>2</sub>max 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

### 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/m<sup>2</sup>; 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

8930

## 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**

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**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*