# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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 circumstance 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 (±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 scienece

**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**
8930

**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 Cereatine 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-reacive protein

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

**Method of measurement**
immunoturbidometric 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 circumstance
**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*