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 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)
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+98 41 1339 3251
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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
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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