

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of downhill running and creatine monohydrate loading on biochemical, inflammatory and performance indices of muscle soreness in male mountain climbers

Protocol summary

Summary

In accordance with the limited studies about the effect of short and long-term creatine supplementation on exercise-induced physiological response, the present study will conduct to identify the effect of downhill running and creatine monohydrate loading on biochemical, inflammatory and performance indices of muscle soreness in male mountain climbers. Methods: Twenty male volunteer mountain climbers (aged 22-28 year, fat 8-12, and VO₂max 50-55 ml/kg/min) in a quasi-experimental, randomized and double-blind design will allocate equally into supplement and placebo groups. Each participant will receive creatine monohydrate or dextrose (0.3 g/kg body weight/day) for five consecutive days (Loading Phase). 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). Biochemical (Serum creatine kinase: CK), inflammatory (Peripheral blood leukocyte count; Serum C-reactive protein: CRP; interleukin-6: IL-6; 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, CRP and IL-6 will measure by photometric, immunoturbidometric and ELISA assays (with commercial Pars-Azmoon and Bendermed 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.

General information

Acronym

Cra2010Etemadian

IRCT registration information

IRCT registration number: **IRCT201011304663N4**

Registration date: **2012-08-01, 1391/05/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-01, 1391/05/11

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

2010-05-26, 1389/03/05

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 creatine monohydrate loading on biochemical, inflammatory and performance indices of muscle soreness in male mountain climbers

Public title
Creatine effect on downhill running-induced damages

Purpose
Basic science

Inclusion/Exclusion criteria
Inclusion criteria :Healthy males; mountain climbers; aged 22-28 years; BMI 18-22 Kg/m²; High jump more than 45 cm; aerobic power more than 50 ml/kg/min; at least 3 years sport history; without any anti-inflammatory and medical drugs during 6 months prior to the study. Exclusion criteria: chronic diseases; injuries; uncontrolled intake of oxidative supplements; uncontrolled intake of anti-inflammatory drugs or stimulants such as caffeine >100 mg/day (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
2010-09-23, 1389/07/01
Ethics committee reference number
8929

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
C-reactive protein

Timepoint
Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement
immunoturbidometric assay

2

Description
IL-6

Timepoint
Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement
ELISA methods with commercial kits

3

Description
Total Serum Creatine kinase (CK)

Timepoint
Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement
Photometric methods with commercial kits (Pars-Azmoon)

4

Description
Peripheral blood leukocyte count

Timepoint
Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement
It will determine by automatic analyzer.

5

Description

Perceived soreness

Timepoint

Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

Talag Scale

6

Description

Muscle circumference

Timepoint

Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

It will determine by flexible tap

7

Description

Lower limb flexibility

Timepoint

Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

Sit and reach test (wells)

8

Description

Lower limb maximal isometric strength

Timepoint

Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

Dynamometric measurement

9

Description

Lower limb power

Timepoint

Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

Sargent vertical jump test

Secondary outcomes

1

Description

Peripheral blood lactate

Timepoint

Before and immediately after downhill running protocol

Method of measurement

It will determine by with commercial Randox kits

2

Description

Serum Total antioxidant capacity (TAC)

Timepoint

Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

by Frap Method.

3

Description

Serum Malondialdehyde

Timepoint

Before and after 5-day creatine supplementation, 30 min before and immediately and 24 hours after downhill running protocol

Method of measurement

by thiobarbituric acid reactive substance (TBARS) and spectrophotometer

Intervention groups

1

Description

Each participant will receive dextrose (0.3 g/kg body weight/day) for five 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 creatine monohydrate (0.3 g/kg body weight/day) for five consecutive days (Loading Phase). 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

The mountain climbing Board of East Azerbaijan

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

University of Tabriz

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