# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Nov 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 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.


## 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
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Iran (Islamic Republic of)
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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**

2010-05-26, 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 scienece

**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-reacive 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 Cereatine 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 circumstance
**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**

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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*