Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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
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

2010-05-26, 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