Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of one section strenuous physical activity & Crocus stavus Supplementation on HSP 70 , IL-6, TNF α in male mountain climbers

Protocol summary

Summary

Objective: This study attempted to investigate acute effect of strenuous physical activity with & without saffron supplementation on heat shock protein 70 (HSP70), interleukin-6 (IL-6) and TNFα in male mountain climbers. Inclusion criteria : with minimum 2 years mountaineering ; Climbing experience at minimum height of 4000 meter ; A minimum height of 3500 m bivouac; who were not smoking; No overweight ;No history of endocrine diseases;No diabetes;No heart disease and chronic disease exclusion criteria : Endocrine diseases ; Diabetes; Heart disease and any disease lack of taking the supplements for any reason; Failure to observe the test conditions such as altitude sports . Eleven male climbers with an age range of 27-37 years old ran at one session physical activity with intensity 80-90% of maximum heart rate for 45 minutes on a -5% slope surface. 3 days after recovery, the subjects were given 300 mg of dried stigmas of saffron in capsules once a day for ten days. Subsequently, the subjects again before, immediately and after one hour physical activity to measure HSP70, IL-6 and TNFα.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052622416N1**
Registration date: **2016-08-15, 1395/05/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-15, 1395/05/25

Registrant information

Name

Fatemeh Jan Bozorgi

Name of organization / entity

Islamic Azad University, Science and Research

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

personal

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2015-12-06, 1394/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of one section strenuous physical activity & Crocus stavus Supplementation on HSP 70 , IL-6, TNF α in male mountain climbers

Public title

Effect of one section strenuous physical activity & Crocus stavus Supplementation on HSP 70 , IL-6, TNF α in male mountain climbers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : with minimum 2 years mountaineering ; Climbing experience at minimum height of 4000 meter ; A minimum height of 3500 m bivouac; who were not smoking; No overweight ;No history of endocrine

diseases;No diabetes;No heart disease and chronic disease exclusion criteria : Endocrine diseases ; Diabetes; Heart disease and any disease lack of taking the supplements for any reason; Failure to observe the test conditions such as altitude sports

Age
From **27 years** old to **37 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **11**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Committee Ethics in biomedical research Science and Research Branch of Islamic Azad University

Street address
Islamic Azad University, Science and Research, Boulevard of Martyrs HESARAK, University Square, the martyr Stari highway, Tehran

City
Tehran

Postal code
1477893855

Approval date
2016-06-19, 1395/03/30

Ethics committee reference number
IR.IAU.SRB.REC.1395.7

Health conditions studied

1

Description of health condition studied
Effect of one section strenuous physical activity & Crocus stavus Supplementation

ICD-10 code
Z00.6,Z00

ICD-10 code description
Examination for normal comparison and control in clinical research programme

Primary outcomes

1

Description
Hsp 70

Timepoint
Before Saffron supplementation: Before physical activity , Immediately after physical activity , 1 hour post-physical activity - After supplementation Saffron : Before physical activity , Immediately after physical activity , 1 hour after physical activity

Method of measurement
Using blood, serum Hsp70 value in Nanograms per deciliter by Kit

2

Description
IL-6

Timepoint
Before Saffron supplementation: Before physical activity , Immediately after physical activity , 1 hour post-physical activity - After supplementation Saffron : Before physical activity , Immediately after physical activity , 1 hour after physical activity

Method of measurement
Using blood, serum IL-6 value in Picograms per deciliter by Kit

3

Description
TNFα

Timepoint
Before Saffron supplementation: Before physical activity , Immediately after physical activity , 1 hour post-physical activity - After supplementation Saffron : Before physical activity , Immediately after physical activity , 1 hour after physical activity

Method of measurement
Using blood, serum TNFα value in Picograms per deciliter by Kit

Secondary outcomes

empty

Intervention groups

1

Description
Saffron supplementation; dose of 300 mg per day; once per day; for 10 days

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
IR Iran Mountaineering & Sport Climbing Federation

Full name of responsible person
Fatemeh Jan Bozorgi

Street address
The Parliament Issue 19, Iranian Revolutionary Guards, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Islamic Azad University, Science and Research

Full name of responsible person
Fatemeh Jan Bozorgi

Street address
Islamic Azad University, Science and Research, Boulevard of Martyrs HESARAK, University Square, the martyr Stari highway, Tehran

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research of Islamic Azad University, Science and Research

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

Name of organization / entity
Islamic Azad University, Science and Research

Full name of responsible person
Fatemeh Jan Bozorgi

Position
Sports Physiology graduate student

Other areas of specialty/work

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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