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

Protocol 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

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

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
Groups that have been masked
None

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

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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**

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### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
empty

**Study Protocol**
empty

**Statistical Analysis Plan**
