

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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 TNF α 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 TNF α .

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)

Phone

+98 21 6684 7082

Email address

fatemeh.janbozorgi@srbiau.ac.ir

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

TNF α

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 TNF α 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

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Web page address

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

Street address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University, Science and Research

Full name of responsible person

Farshad Gazalian

Position

PhD Sports Physiology

Other areas of specialty/work

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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