

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effects of one bout of strenuous physical activity and black mulberry supplementation on some pro-inflammatory factors in female basketball players

#### Protocol summary

##### Summary

This research aims to discover the effects of Black Mulberry on serum concentration of Interleukin-6 and Tumor Necrosis Factor-alfa after one bout of strenuous exercise in female basketball players. Including criteria: female basketball players, ages 20 to 30 years with at least 2 years of professional basketball playing and with no recent history of nutritional supplement usage were selected to participate in the trial. Excluding criteria: recent exercise induced injury, non-standard BMI, high body fat percentage. Study Population: female basketball players Number of Participants: 15 Study intervention: 300 milliliters of Black Mulberry juice Intervention time and period: 10 days, during exercise sessions or in snacks First impression: decrease in pro-inflammatory cytokines

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015100524358N1**  
Registration date: **2016-07-20, 1395/04/30**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-20, 1395/04/30

##### Registrant information

##### Name

Negar Borghei

##### Name of organization / entity

Science and Research Islamic Azad University

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research of Islamic Azad University  
Science and Research Branch

##### Expected recruitment start date

2015-07-06, 1394/04/15

##### Expected recruitment end date

2015-09-26, 1394/07/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of one bout of strenuous physical activity and black mulberry supplementation on some pro-inflammatory factors in female basketball players

##### Public title

The effect of Black Mulberry on inflammation caused by strenuous physical activity

##### Purpose

Other

##### Inclusion/Exclusion criteria

Inclusion Criteria: >2 years athletic activity; female; 20-30 years old; BMI range of 19-27; Standard Body Fat Percentage. Exclusion Criteria: metabolic disorders such as diabetes; chronic heart and artery diseases; smoking; alcohol consumption.

##### Age

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **14****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**Ethics in biomedical research Science and Research  
Branch of Islamic Azad University**Street address**

Sciences &amp; Research Branch, Hesarak

**City**

Tehran

**Postal code****Approval date**

2016-06-19, 1395/03/30

**Ethics committee reference number**

IR.IAU.SRB.REC.1395.6

**Health conditions studied****1****Description of health condition studied**Inflammation caused by strenuous physical activity,  
Effect of one bout of strenuous physical activity and  
Black Mulberry supplementation**ICD-10 code**

Z00.6,Z00.

**ICD-10 code description**Examination for comparison and control in clinical  
research programme, General medical examination**Primary outcomes****1****Description**

Interleukin-6

**Timepoint**before, immediately after, after an hour (before and after  
supplementation)**Method of measurement**Serum concentrations measured by high sensitivity  
Diaclone kit**2****Description**

TNF-alfa

**Timepoint**before, immediately after, after an hour (before and after  
supplementation)**Method of measurement**Serum concentrations measured by high sensitivity  
Diaclone kit**Secondary outcomes****1****Description**

Creatine Kinase

**Timepoint**

before,immediately after, after an hour, after 48 hours

**Method of measurement**

Serum concentrartions

**2****Description**

Lactate Dehydrogenase

**Timepoint**

before,immediately after, after an hour, after 48 hours

**Method of measurement**

Serum concentrartions

**Intervention groups****1****Description**Black Mulberry pulped Juice, 300 grams, used before,  
during and after exercise sessions or between meals for  
10 days.**Category**

Other

**2****Description**

Basketball Exercise Simulation for 87 minutes

**Category**

Other

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**

Science and Research Branch Islamic Azad University

**Full name of responsible person**

Farshad Ghazalian

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Hesarak Blvd, University Square, Sattari Highway

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Science and Research Islamic Azad University

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Science and Research Islamic Azad University

**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**

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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*