

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of propolis supplementation on athletic performance and inflammatory markers and oxidative stress

#### Protocol summary

##### Study aim

This clinical trial aims to assess the effect of propolis on oxidative stress status, inflammation, and exercise performance.

##### Design

This study is a double-blind, placebo-controlled, randomized phase 2 clinical trial evaluating the effect of propolis on oxidative stress status, inflammation, and exercise performance. In this study, 54 eligible participants will be randomly assigned to either the intervention or the control group. The randomization sequence will be generated using a random-number table.

##### Settings and conduct

The study participants will be recruited from new cadets entering the Islamic Republic of Iran Army University of Medical Sciences. Participants who meet entry criteria will be randomly assigned to the propolis group or the placebo group. The participant's assignment will be concealed from all participants and investigators, with the exception of the study pharmacist and care provider.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria are male sex, exerciser, age of 20 to 40 years, and body mass index of 18.5 to 25 kg/square meter. The exclusion criteria are cardiovascular diseases, diabetes, metabolic diseases, musculoskeletal dysfunction, sensitivity to propolis, and regular use of antioxidant supplements and anti-inflammatory drugs.

##### Intervention groups

Participants in the intervention group will receive an identical propolis tablet (containing 450 mg Iranian green propolis extract and 150 mg microcrystalline cellulose) twice daily for 4 weeks. Participants in the placebo group will receive an identical tablet placebo (containing 590 mg microcrystalline cellulose and 10 mg edible colors) twice daily for 4 weeks.

##### Main outcome variables

Glutathione concentration Aerobic capacity Fatigue Index

Anaerobic Power

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180824040857N2**

Registration date: **2020-10-18, 1399/07/27**

Registration timing: **retrospective**

Last update: **2020-10-18, 1399/07/27**

Update count: **0**

##### Registration date

2020-10-18, 1399/07/27

##### Registrant information

##### Name

Davoud Soleimani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3800 2423

##### Email address

DAVOUD.SOLEIMANI@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-05, 1399/06/15

##### Expected recruitment end date

2020-09-12, 1399/06/22

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of propolis supplementation on athletic performance and inflammatory markers and oxidative stress

### Public title

Propolis supplementation AND Athletes

### Purpose

Other

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Male gender Exerciser Subjects with Body Mass Index

#### Exclusion criteria:

Female gender Cardiovascular diseases Metabolic diseases Diabetes Musculoskeletal Dysfunction Use of Propolis Supplement Use of Anti-inflammatory Drugs

### Age

From **20 years** old to **40 years** old

### Gender

Male

### Phase

2

### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **54**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Eligible participants will be randomly assigned, in a ratio of 1:1, to either propolis group or placebo group. Randomization will be stratified according to the participant's age (20-30 vs. 31-40 years). Randomization sequences will be prepared by the study's pharmacist with the use of a random number table.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Assignment of participants to the study groups will be concealed from participants and investigators, with the exception of the study pharmacist and care provider, until the end of the study and data analysis. The study pharmacist who will be aware of the assignments will prepare the placebo tablets similar to the propolis tablet in color, odor, taste, shape, size, and weight. Drug containers will be the same in terms of shape, color, odor, size, and weight and will be kept inside numbered, opaque, and sealed envelopes which will be completely impermeable to light.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of the Islamic Republic of Iran Army University of Medical Sciences

##### Street address

The Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718541

#### Approval date

2020-09-02, 1399/06/12

#### Ethics committee reference number

IR.AJAUMS.REC.1399.107

## Health conditions studied

### 1

#### Description of health condition studied

Sports Nutrition

#### ICD-10 code

M99

#### ICD-10 code description

Biomechanical lesions, not elsewhere classified

## Primary outcomes

### 1

#### Description

Fatigue Index

#### Timepoint

At the beginning of the study and fourth week of intervention

#### Method of measurement

RAST test

### 2

#### Description

Anaerobic Power

#### Timepoint

At the beginning of the study and fourth week of intervention

#### Method of measurement

RAST test

### 3

**Description**

Aerobic Capacity

**Timepoint**

At the beginning of the study and fourth week of intervention

**Method of measurement**

Cooper test

### 4

**Description**

interleukin-6

**Timepoint**

At the beginning of the study and fourth week of intervention

**Method of measurement**

ELISA

### 5

**Description**

interleukin-10

**Timepoint**

At the beginning of the study and fourth week of intervention

**Method of measurement**

ELISA

### 6

**Description**

catalase activity

**Timepoint**

At the beginning of the study and fourth week of intervention

**Method of measurement**

colorimetric method

### 7

**Description**

superoxide dismutase activity

**Timepoint**

At the beginning of the study and fourth week of intervention

**Method of measurement**

colorimetric method

### 8

**Description**

Glutathione concentration

**Timepoint**

At the beginning of the study and fourth week of intervention

**Method of measurement**

colorimetric method

## Secondary outcomes

### 1

**Description**

Alanine aminotransferase

**Timepoint**

At the beginning of the study and fourth week of intervention

**Method of measurement**

Colorimetric method

### 2

**Description**

Aspartate aminotransferase

**Timepoint**

At the beginning of the study and fourth week of intervention

**Method of measurement**

Colorimetric method

## Intervention groups

### 1

**Description**

Intervention group: Participants in the intervention group will receive an identical propolis tablet (450 mg, containing 300 mg Iranian green propolis extract and 150 mg microcrystalline cellulose) three times a day, before breakfast, lunch, and dinner, for 4 weeks. All tablets are prepared by the Reyhan Naghsh Jahan Pharmaceutical Co., Isfahan, Iran.

**Category**

Treatment - Other

### 2

**Description**

Control group: Participants in the control group will receive an identical placebo tablet (450 mg, containing 443 mg microcrystalline cellulose and 7 mg edible colors) three times a day, before breakfast, lunch, and dinner, for 4 weeks. All tablets are prepared by the Reyhan Naghsh Jahan Pharmaceutical Co., Isfahan, Iran.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

The Islamic Republic of Iran Army University of Medical Sciences

**Full name of responsible person**

Said Hadi

**Street address**

The Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran

**City**

Tehran

**Province**  
Tehran  
**Postal code**  
1411718541  
**Phone**  
+98 21 4382 2284  
**Email**  
s.hadinu@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Sanaz Zargar Balaye Jame  
**Street address**  
The Islamic Republic of Iran Army University of  
Medical Sciences, Etemadzadeh street, West Fatemi  
street, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411718541  
**Phone**  
+98 21 8609 6350  
**Email**  
s.hadinu@yahoo.com

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Vice-Chancellor for Research, The Islamic Republic of  
Iran Army University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Said Hadi  
**Position**  
Assistant Professor  
**Latest degree**

Master

#### Other areas of specialty/work

Nutrition

#### Street address

The Islamic Republic of Iran Army University of  
Medical Sciences, Etemadzadeh street, West Fatemi  
street, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1411718541

#### Phone

+98 21 4382 2284

#### Email

s.hadinu@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Said Hadi  
**Position**  
Assistant professor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
The Islamic Republic of Iran Army University of  
Medical Sciences, Etemadzadeh street, West Fatemi  
street, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411718541  
**Phone**  
+98 21 4382 2284  
**Email**  
s.hadinu@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Said Hadi  
**Position**  
Assistant Professor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
The Islamic Republic of Iran Army University of

Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1411718541

**Phone**

+98 21 4382 2284

**Email**

s.hadinu@yahoo.com

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles.

**When the data will become available and for how long**

The non-identifiable individual participant data will become available after the publication of the relevant articles.

**To whom data/document is available**

The non-identifiable individual participant data will become available to other researchers in academic institutions.

**Under which criteria data/document could be used**

The non-identifiable individual participant data can only be used for research.

**From where data/document is obtainable**

The non-identifiable individual participant data will be obtainable by sending an e-mail to Mr. Said Hadi (s.hadinu@yahoo.com).

**What processes are involved for a request to access data/document**

Other researchers in academic institutions can send their request by e-mail to Mr. Said Hadi (s.hadinu@yahoo.com). The data will be sent to them after consulting and approving the research team.

**Comments**