Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 prepared 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
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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
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The Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh street, West Fatemi street, Tehran
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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
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Person responsible for updating data

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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