Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of royal jelly supplement on athlete performance and gene expressions in endurance-trained men: A double-blind, cross-over, clinical trial

Protocol summary

Study aim

Determining the effect of the royal jelly dietary supplement on the maximum rate of oxygen consumption, oxidative stress indices following endurance activity, and the expression of PGC-1α and Nrf2 genes in trained men

Design

A randomized, double-blind, cross-over, placebo-controlled, phase 2 clinical trial

Settings and conduct

The study participants will be recruited from the Faculty of Sport Sciences, Razi University, Kermanshah. Eligible participants will be randomly assigned in a ratio of 1:1 to either intervention or control group. Participants in the intervention group will take 1000 mg/day of royal jelly and the control group will take a placebo for 2 weeks. According to the cross-over design of the study, we consider 2 weeks as a wash-out period to eliminate the intervention and placebo effect. After that, the assignments will be changed between the two groups and the study will continue for two more weeks.

Participants/Inclusion and exclusion criteria

Men 18 to 44 years of age are eligible for inclusion in the trial if they provide written informed consent and have regular endurance activities at least 3 times per week in the last 6 months. We also exclude persons who have a history of any acute or chronic respiratory diseases, heart diseases, diabetes mellitus, metabolic disorders, musculoskeletal diseases, and injuries during training or exercise, use dietary and antioxidant supplements (such as vitamin E, vitamin C, β-carotene, selenium, and royal jelly) and anti-inflammatory drugs in the last 3 months, follow specific dietary programs; and have an allergy to bee products and royal jelly.

Intervention groups

Participants in the intervention group will take 500 mg of royal jelly tablets, and the control group will take placebo tablets (containing 500 mg of microcrystalline cellulose) twice daily after breakfast and dinner for 2 weeks.

Main outcome variables

Endurance performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231209060310N1**
Registration date: **2023-12-21, 1402/09/30**
Registration timing: **prospective**

Last update: **2023-12-21, 1402/09/30**
Update count: **0**

Registration date

2023-12-21, 1402/09/30

Registrant information

Name

Mahsa Miryan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3710 2015

Email address

mahsa.miran@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-11-20, 1403/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of royal jelly supplement on athlete performance and gene expressions in endurance-trained men: A double-blind, cross-over, clinical trial

Public title

Effect of royal jelly in athletes

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Having regular endurance activities at least 3 times per week in the last 6 months Providing written informed consent

Exclusion criteria:

Use of antioxidant supplements (for example, vitamin E, vitamin C, β-carotene, and selenium), royal jelly, or anti-inflammatory drugs in the last three months History of any acute or chronic respiratory diseases, heart diseases, diabetes mellitus, and metabolic disorders Use of any dietary supplements in the last three months Following specific dietary programs Having musculoskeletal diseases or injuries History of any injuries during training or exercise Allergy to bee products and royal jelly

Age

From **18 years** old to **44 years** old

Gender

Male

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization in this study is based on the simple randomization method without stratification. The randomization sequence will be generated with the use of a computer-generated random-number table by the study statistician. Each random sequence will be recorded on a card, and then all cards will be sealed in sequentially numbered opaque envelopes. Envelopes will be opened in their numbered sequence after the enrollment of eligible participants. These participants will be randomly assigned in a 1:1 ratio in a blinded manner to the intervention or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this trial, random sequences will be placed in sequentially numbered opaque envelopes and remain concealed until enrollment. Eligible participants will be randomly assigned in a 1:1 ratio in a blinded manner to the intervention or control groups. Participants and investigators, except the study statistician, will be concealed from the study-group assignment until the end of the trial and data analyses. The placebo tablet will be identical in terms of shape, color, size, odor, and weight to the royal jelly tablet. All tablets will be enclosed in similar containers.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Kermanshah University of Medical Sciences

Street address

Faculty of Nutrition Sciences and Food Industry, next to Farabi Hospital, Isar Square, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6719851552

Approval date

2023-11-28, 1402/09/07

Ethics committee reference number

IR.KUMS.REC.1402.419

Health conditions studied

1

Description of health condition studied

Sports Nutrition

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum Malondialdehyde

Timepoint

Day 1, 14, 28, and 42 of the study

Method of measurement

Colorimetric method

2

Description
Serum total antioxidant status
Timepoint
Day 1, 14, 28, and 42 of the study
Method of measurement
Colorimetric method

3

Description
Serum total oxidative status
Timepoint
Day 1, 14, 28, and 42 of the study
Method of measurement
Colorimetric method

4

Description
Aerobic Capacity
Timepoint
Day 1, 14, 28, and 42 of the study
Method of measurement
Bruce test

5

Description
Nrf2 gene
Timepoint
Day 1, 14, 28, and 42 of the study
Method of measurement
PCR

6

Description
PGC1-α gene
Timepoint
Day 1, 14, 28, and 42 of the study
Method of measurement
PCR

Secondary outcomes

1

Description
systolic blood pressure
Timepoint
Day 1, 14, 28, and 42 of the study
Method of measurement
Sphygmomanometer

2

Description
Diastolic blood pressure
Timepoint
Day 1, 14, 28, and 42 of the study
Method of measurement
Sphygmomanometer

3

Description
Post-exercise blood pressure
Timepoint
Day 1, 14, 28, and 42 of the study
Method of measurement
Sphygmomanometer

Intervention groups

1

Description
Intervention group: Participants will take 500 mg of royal jelly tablets twice daily after breakfast and dinner for 2 weeks. The royal jelly tablets will be prepared by the School of Pharmacy, Mashhad University of Medical Sciences, Iran.
Category
Treatment - Drugs

2

Description
Control group: Participants will take 500 mg of placebo tablets (containing 500 mg of microcrystalline cellulose) twice daily after breakfast and dinner for 2 weeks. The placebo tablets will be prepared by the School of Pharmacy, Mashhad University of Medical Sciences, Iran.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sports Laboratory, Faculty of Sports Sciences, Razi University, Kermanshah
Full name of responsible person
Dr. Vahid Tadibi
Street address
Faculty of Sports Sciences, Razi University, University St., Taq Bostan, Kermanshah
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Phone
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vtadibi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Cyrus Jalili

Street address
Deputy for Research and Technology, Kermanshah University of Medical Sciences, Building No. 2, Shahid Beheshti Boulevard, Kermanshah

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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Yahya Pasdar

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Faculty of Nutrition Sciences and Food Industry, next to Farabi Hospital, Isar Square, Kermanshah

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Mahsa Miryan

Position
Ph.D. student

Latest degree
Master

Other areas of specialty/work
Nutrition

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miryanm2014@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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 Dr. Yahya Pasdar. (e-mail address: yahya.pasdar@kums.ac.ir)

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

Other researchers in academic institutions can send their requests by e-mail to Dr. Yahya Pasdar. The data will be sent to them after consulting and approving the research team.

Comments