Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Phoenix Dactylifera pollen supplementation on eccentric resistance exercise-induced delayed-onset muscle soreness in female athletes

Protocol summary

Study aim

This study aimed to investigate the effects of Phoneix Dactylifera pollen on indices of delayed-onset muscle soreness following a bout of eccentric resistance exercise.

Design

A double-blind, randomized, placebo-controlled trial

Settings and conduct

Thirty-six female athletes have participated. Participants were equally divided into groups including 100 mg of PD, 200 mg of PD and 100 mg of starch as placebo. The participant has a 10-day supplement consumption. After that, a bout of leg curl performed. The blood samples were collected before and several times after exercise (1, 2, 3, 4, day).

Participants/Inclusion and exclusion criteria

The inclusion criteria were: complete skeletal and neuromuscular health, no presence of any serious medical conditions including cardiovascular diseases, diabetes, hypertension, hepatic diseases, renal diseases and respiratory disorders, no history of food allergies, and no consumption of antioxidants or anti-inflammatory supplements. Exclusion criteria included incidence of any chronic or acute disease during the study, non-compliance with the study protocol, use of tobacco products, alcohol consumption, recent surgery or illness, and use of any medicine or dietary supplements such as antioxidant supplement (vitamin C, E,.) and anti-inflammatory drugs (aspirin subgroups) within three months prior to the study.

Intervention groups

Intervention group 1: 100 mg capsules of date pollen were consumed for 10 days and one capsule daily.
Intervention group 2: 200 mg capsules of date pollen were consumed for 10 days and one capsule daily.
Control group: 200 mg capsules of starch as placebo, consumed for 10 days and one capsule daily.

Main outcome variables

Lactate dehydrogenase, creatine kinase, alanine aminotransferase, aspartate aminotransferase, lymphocytes, neutrophils, thigh circumference, angel of leg extension and Sargent jumping

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190103042219N2**
Registration date: **2020-05-02, 1399/02/13**
Registration timing: **retrospective**

Last update: **2020-05-02, 1399/02/13**
Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name

Mohammad Ali Azarbayjani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-13, 1399/01/25

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date
2020-04-14, 1399/01/26
Actual recruitment end date
2020-04-19, 1399/01/31
Trial completion date
2020-05-05, 1399/02/16

Scientific title
The effect of Phoenix Dactylifera pollen supplementation on eccentric resistance exercise-induced delayed-onset muscle soreness in female athletes

Public title
Phoneix Dactylifera pollen and delayed-onset muscle soreness indices
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Gender: Women Athlete Present in the Department of Physical Education, Central Tehran Branch, Islamic Azad Univirsity Age limitation (22-26 years old)
Exclusion criteria:
Having chronic or acute disease Use of tobacco products Alcohol consumption Recent surgery or illness Use of any medicine or dietary supplements
Age
From **22 years** old to **26 years** old
Gender
Female

Phase
N/A
Groups that have been masked

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

Sample size
Target sample size: **36**
Actual sample size reached: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Computerization was performed using a computer and a simple randomization method. The method used by the computer was that the computer selects random numbers between 0 and 1. Values less than 0.33 in the control group and values between 0.33 and 0.66 in the first intervention group (100 mg dose supplement) and values greater than 0.66 were in the second intervention group (200 mg dose supplement). Thus, 36 subjects were randomly divided into three groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants were identified using the codes instead of their actual names. A third party was asked to classify the participants randomly, using the (labelled) codes. Study groups had codes instead of names. The laboratory was uninformed from name of groups and only used the codes. Groups codes were used for statistical analysis. The supplement and placebo participants were unaware of their own group label.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Islamic Azad University, Gachsaran Branch
Street address
Gachsaran Branch. Islamic Azad University, Modarress Street, Gachsaran, Kohgiluyeh and Boyer-Ahmad Province, Iran.
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Province
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Postal code
7581863876
Approval date
2020-04-12, 1399/01/24
Ethics committee reference number
IR.IAU.IAUG.REC.1399.009

Health conditions studied

1

Description of health condition studied
Delayed-onset muscle soreness
ICD-10 code
G71
ICD-10 code description
Primary disorders of muscles

Primary outcomes

1

Description
Lactate dehydrogenase
Timepoint
Before exercise, 1,2,3 and 4 days after exercise
Method of measurement
ELISA Kit

2

Description

Creatine kinase

Timepoint

Before exercise, 1,2,3 and 4 days after exercise

Method of measurement

ELISA Kit

3

Description

Alanine aminotransferase

Timepoint

Before exercise, 1,2,3 and 4 days after exercise

Method of measurement

ELISA Kit

4

Description

Aspartate aminotransferase

Timepoint

Before exercise, 1,2,3 and 4 days after exercise

Method of measurement

ELISA Kit

5

Description

Lymphocytes

Timepoint

Before exercise, 1,2,3 and 4 days after exercise

Method of measurement

ELISA Kit

6

Description

Neutrophils

Timepoint

Before exercise, 1,2,3 and 4 days after exercise

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Angel of leg extension

Timepoint

Before exercise, 1,2,3 and 4 days after exercise

Method of measurement

Goniometer

2

Description

Thigh circumference

Timepoint

Before exercise, 1,2,3 and 4 days after exercise

Method of measurement

Meter

3

Description

Sargent jumping

Timepoint

Before exercise, 1,2,3 and 4 days after exercise

Method of measurement

Sargent test

Intervention groups

1

Description

Intervention group 1: Phoneix Dactylifera pollen (100mg). Participants consumed the 100 mg Phoneix Dactylifera pollen supplement for 10 days (one capsule a day). Phoenix dactylifera pollen powder purchased from the agriculture ministry and extracted.

Category

Treatment - Other

2

Description

Intervention group 2: Phoneix Dactylifera pollen (200mg). Participants consumed the 200 mg Phoneix Dactylifera pollen supplement for 10 days (one capsule a day). Phoenix dactylifera pollen powder purchased from the agriculture ministry and extracted.

Category

Treatment - Other

3

Description

Control group: Starch (200mg). Participants in this group received 200 mg of starch for 10 days as placebo (1 capsule per day).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Central Tehran Branch, Department of Exercise physiology

Full name of responsible person

Dr. Maghsoud Peeri

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Central Tehran Branch, Islamic Azad University, Sohanak Neighborhood, Artesh Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Email
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Web page address
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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
Central Tehran Branch, Islamic Azad University
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
Central Tehran Branch, Islamic Azad University
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Dr. Mohammad Ali Azarbayjani
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Full professor
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available