Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Effectiveness of Bee Pollen supplementation on hematological indices, iron stores, and aerobic performance in women with iron deficiency anemia

Protocol summary

Study aim

To determine the effectiveness of bee pollen supplementation on hematological indices, iron stores, and aerobic performance in women with iron deficiency anemia

Design

Randomized, double blind, parallel-group clinical trial in women with iron deficiency anemia

Settings and conduct

Eligible participants will be randomly allocated to bee pollen or placebo groups. The intervention will be administered for 8 weeks, and hematological indices, iron stores, and aerobic performance will be assessed before and after the intervention. Participants and researchers conducting the assessments will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Women aged 18 to 45 years with iron deficiency anemia, hemoglobin 9 to 12 g/dL, and serum ferritin below 30 ng/mL; no use of iron supplements, iron containing multivitamins, or antioxidants during the previous 4 weeks; no regular use of nonsteroidal anti inflammatory drugs during the previous 2 weeks; no history of allergy to bee products; no chronic inflammatory, autoimmune, diabetic, hepatic, or renal disease; not pregnant or breastfeeding

Intervention groups

Intervention group: 1600 mg of bee pollen daily, two 800 mg capsules, for 8 weeks; Control group: two placebo capsules containing wheat starch daily for 8 weeks

Main outcome variables

Red blood cell count; blood hemoglobin level; hematocrit percentage; serum ferritin level; serum iron level; transferrin saturation percentage; total iron binding capacity; maximal oxygen consumption; time to complete the distance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181125041749N6**
Registration date: **2026-08-26, 1405/06/04**
Registration timing: **prospective**

Last update: **2026-08-26, 1405/06/04**
Update count: **0**

Registration date

2026-08-26, 1405/06/04

Registrant information

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Name of organization / entity
Alzahra University
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Iran (Islamic Republic of)
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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-10-22, 1405/07/30

Expected recruitment end date

2027-01-20, 1405/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Bee Pollen supplementation on hematological indices, iron stores, and aerobic performance in women with iron deficiency anemia

Public title

Effectiveness of Bee Pollen supplementation on hematological indices, iron stores, and aerobic performance in women with iron deficiency anemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18–45 years Hemoglobin (Hb) level of 9–12 g/dL (mild to moderate anemia in non-pregnant women) Serum ferritin level below 30 ng/mL (depleted iron stores) No use of iron supplements, iron-containing multivitamins, or antioxidant supplements during the 4 weeks prior to the study No regular use of nonsteroidal anti-inflammatory drugs (NSAIDs) during the 2 weeks prior to the study No history of hypersensitivity to bee products No history of chronic inflammatory, autoimmune, diabetic, hepatic, or renal diseases No hematological disorders other than iron deficiency anemia Not pregnant or breastfeeding No severe obesity (BMI <35 kg/m²) Willingness to participate and complete the 8-week study period

Exclusion criteria:

History of hypersensitivity to bee products History of chronic inflammatory, autoimmune, diabetic, hepatic, or renal diseases Hematological disorders other than iron deficiency anemia Pregnancy or breastfeeding Severe obesity (BMI ≥ 35 kg/m²) Use of iron supplements, iron-containing multivitamins, or antioxidant supplements during the 4 weeks prior to the study Regular use of nonsteroidal anti-inflammatory drugs (NSAIDs) during the 2 weeks prior to the study Unwillingness to participate and complete the 8-week study period Severe anemia (hemoglobin < 9 g/dL) or anemia due to other causes (hemoglobin > 12 g/dL) Inability to perform the exercise test due to musculoskeletal, cardiorespiratory, or coordination problems (based on test termination criteria such as dizziness, ataxia, severe hypotension, etc.)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to the study groups using simple randomization based on a random number table. The individual participant will be the unit of randomization. Eligible participants, after confirmation of the inclusion criteria and completion of the General Health Questionnaire and the Physical Activity Readiness Questionnaire (PAR-Q), will be randomly assigned to either the intervention group (bee pollen) or the control group (placebo), with 14 participants in each group. No stratified or cluster randomization will be used. The supplement and placebo capsules will be identical in appearance, and the group codes will remain confidential until completion of data analysis, after which they will be revealed. A third party will be aware of the capsule contents and group codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted in a double-blind manner. Participants and the researchers conducting the assessments will be unaware of the participants' group allocation and the contents of the capsules they receive. The bee pollen and placebo capsules will be identical in appearance. The group codes will remain confidential until completion of the data analysis and will then be revealed. Only a third party will be aware of the capsule contents and the corresponding group codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Alzahra University

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Alzahra University, Deh-e-Vanak St.

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Approval date

2026-07-01, 1405/04/10

Ethics committee reference number

IR.ALZAHRA.REC.1405.065

Health conditions studied

1

Description of health condition studied

Iron deficiency anemia

ICD-10 code

D50.9

ICD-10 code description

Iron deficiency anemia, unspecified

Primary outcomes

1

Description

Blood hemoglobin level

Timepoint

At baseline before the intervention and after 8 weeks of intervention

Method of measurement

Measurement of hemoglobin concentration in venous blood samples using a standard laboratory method

Secondary outcomes

1

Description

Red blood cell count (RBC)

Timepoint

At baseline, before the intervention, and after 8 weeks of intervention

Method of measurement

Measurement of red blood cell count in venous blood samples using an automated hematology analyzer

2

Description

Blood hemoglobin level (Hb)

Timepoint

At baseline, before the intervention, and after 8 weeks of intervention

Method of measurement

Measurement of blood hemoglobin level in venous blood samples using an automated hematology analyzer

3

Description

Hematocrit percentage (Hct)

Timepoint

At baseline, before the intervention, and after 8 weeks of intervention

Method of measurement

Measurement of hematocrit percentage in venous blood samples using an automated hematology analyzer

4

Description

Serum ferritin level

Timepoint

At baseline, before the intervention, and after 8 weeks of intervention

Method of measurement

Measurement of serum ferritin level in venous blood samples using a standard laboratory method

5

Description

Serum iron level

Timepoint

At baseline, before the intervention, and after 8 weeks of intervention

Method of measurement

Measurement of serum iron level in venous blood samples using a standard laboratory method

6

Description

Transferrin saturation percentage (TSAT)

Timepoint

At baseline, before the intervention, and after 8 weeks of intervention

Method of measurement

Calculation of transferrin saturation percentage based on serum iron level and total iron-binding capacity

7

Description

Total iron-binding capacity (TIBC)

Timepoint

At baseline, before the intervention, and after 8 weeks of intervention

Method of measurement

Measurement of total iron-binding capacity in venous blood samples using a standard laboratory method

8

Description

Maximal oxygen consumption (VO2max)

Timepoint

At baseline, before the intervention, and after 8 weeks of intervention

Method of measurement

Estimation of maximal oxygen consumption using the Rockport One-Mile Walking Test

9

Description

Time to complete the distance

Timepoint

At baseline, before the intervention, and after 8 weeks of intervention

Method of measurement

Measurement of the time required to complete one mile in the Rockport One-Mile Walking Test using a stopwatch

Intervention groups

1

Description

Intervention group: Participants will receive 1,600 mg of bee pollen orally per day (two 800-mg capsules) for 8 weeks, administered 30 minutes before the main breakfast and dinner meals. The bee pollen supplement will be obtained from Farvardin Company, Iran. Each capsule contains 800 mg of pure bee pollen.

Category

Treatment - Other

2

Description

Control group: Participants will receive two placebo capsules orally per day for 8 weeks, with each capsule containing 800 mg of wheat starch. The placebo capsules will be identical to the bee pollen capsules in appearance, color, and packaging.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra University, Faculty of Sport Sciences

Full name of responsible person

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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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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alzahra 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

Alzahra University

Full name of responsible person

Fahimeh Kazemi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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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
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data relating to subjects will be shared as unidentified.

When the data will become available and for how long
Six months after the publication of the article.

To whom data/document is available
All researchers

Under which criteria data/document could be used
The data may be used for citation purposes, provided that the source is acknowledged.

From where data/document is obtainable
Fahimeh Kazemi

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

Comments