Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of eight weeks of combined training (resistance-aerobic) and propolis supplementation on serum levels of adipolin (CTRP12) and secretory protein associated with secretory curvature (SFRP5) and Interleukin-6 (IL-6) and glycemic indexes in women with type 2 diabetes with dyslipidemia

Protocol summary

Study aim

Evaluation of a course of combined training and consumption of propolis supplement on serum level of adipolin and inflammatory factor and glycemic indexes in type 2 diabetic women with dyslipidemia

Design

This study was a randomized, placebo-controlled, clinical trial with parallel and double-blind groups on 40 participants using available sampling method. Randomization is performed by a person who does not participate in the study. The researcher numbers the subjects' names and puts the numbers in an envelope, and another person enters the names, and the participants enter the intervention or placebo groups.

Settings and conduct

The statistical population of this study is type 2 diabetic women in Shiraz. 40 of these people are selected based on the inclusion and exclusion criteria of the study and after completing the consent form, randomly and blindly divided into 4 groups (exercise + propolis supplement, exercise + Placebo, supplement group and placebo group) are divided. None of the subjects will be aware of the status of supplementation and groupings.

Participants/Inclusion and exclusion criteria

Inclusion criteria, female sex and fasting glucose of subjects equal to or greater than 126 mg / dL, triglyceride greater than 150 mg / dL; The criterion for not entering, any skin or gastrointestinal allergies to propolis and is to have any underlying disease.

Intervention groups

Combined exercise includes 20 minutes of aerobic exercise and 45 minutes of resistance training, 3-4 sessions per week + propolis supplement (3 propolis tablets at a dose of 300 mg), combined exercise + placebo (3 placebo tablets with the same protocol as the intervention group), supplement group and A group of placebos are divided. The study participants did not know that their pills contained a Propolis supplement or a placebo.

Main outcome variables

serum levels of adipolin and SFRP5 and Interleukin-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211229053561N1**
Registration date: **2022-01-26, 1400/11/06**
Registration timing: **prospective**

Last update: **2022-01-26, 1400/11/06**
Update count: **0**

Registration date

2022-01-26, 1400/11/06

Registrant information

Name
Fatemeh Moayedi
Name of organization / entity
Islamic Azad University of Khorasgan Branch
Country
Iran (Islamic Republic of)
Phone
+98 71 3632 2954
Email address
fatemeh_m8040@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-02-08, 1400/11/19
Expected recruitment end date
2022-03-15, 1400/12/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of eight weeks of combined training (resistance-aerobic) and propolis supplementation on serum levels of adipolin (CTRP12) and secretory protein associated with secretory curvature (SFRP5) and Interleukin-6 (IL-6) and glycemic indexes in women with type 2 diabetes with dyslipidemia

Public title
The effect of exercise and bee propolis supplement on type 2 diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Fasting blood sugar greater than 126 mg / dL Oral glucose tolerance test equal to or greater than 200 mg / dL Glycosylated hemoglobin 6/5 % or higher Body mass index between 27 Up to 35 Age 40 to 60 years
Exclusion criteria:
Insulin use Having cardiovascular disease Musculoskeletal disease Liver disease Kidney disease Thyroid disorder Having a history of regular physical activity for at least the last six months
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The statistical population of this study is women 40 to 60 years old with type 2 diabetes in Shiraz who will be selected by clinical trial. According to the corona conditions, the sample size is estimated to be 40 people and then the subjects are divided into 4 groups using simple random sampling, which are: The first group: propolis supplement (10 people). The second group: propolis supplement and exercise (10 people); The third group: placebo (10 people), the fourth group: exercise and placebo (10 people) will be divided. None of the subjects will be aware of the status of supplements and groupings. The researcher numbers the names of the subjects and puts the numbers in the envelope, and another person enters the names and puts them in 4 groups, respectively.
Blinding (investigator's opinion)
Double blinded
Blinding description
All study participants (subjects) are aware that propolis supplementation is to be considered in this study, but are not aware of the contents of the capsule (placebo or propolis) they are taking. The main researchers of the research (student, supervisor and consultant professor) will not be informed which capsule (placebo or propolis) which subject is consuming until the end of the research. Laboratory personnel who are responsible for sampling and measuring variables are also unaware of which subjects are taking which capsules (placebo or supplement). Patients in the supplement and exercise + supplement group take 3 tablets with 300 mg of propolis for eight weeks three times a day one hour after each meal. The placebo and placebo + exercise groups receive the same amount of placebo. The placebo and propolis supplement are placed inside the capsule in exactly the same way.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Khorasgan Branch
Street address
University Boulevard, Arghavanieh, East J. Street
City
Khorasgan
Province
Isfehan
Postal code
۸۱۵۵۱-۳۹۹۹۸
Approval date
2021-12-22, 1400/10/01
Ethics committee reference number
IR.IAU.KHUISF.REC.1400.265

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Interleukin- 6
Timepoint
Before the intervention and 48 hours after the intervention
Method of measurement
Biochemical and laboratory methods

2

Description
Adipolin
Timepoint
Before the intervention and 48 hours after the intervention
Method of measurement
Biochemical and laboratory methods

3

Description
Secreted frizzled-related protein 5
Timepoint
Before the intervention and 48 hours after the intervention
Method of measurement
Biochemical and laboratory methods

Secondary outcomes

1

Description
Fasting blood glucose
Timepoint
Before and after the protocol
Method of measurement
Mg /dL by blood test

2

Description
triglyceride
Timepoint
Before and after the protocol
Method of measurement
Laboratory and biochemical methods

3

Description
Low density lipoprotein cholesterol
Timepoint
Before and after the protocol
Method of measurement
Laboratory and biochemical methods

4

Description
High-density lipoprotein cholesterol
Timepoint
Before and after the protocol
Method of measurement
Laboratory and biochemical methods

5

Description
Insulin
Timepoint
Before and after the protocol
Method of measurement
Laboratory and biochemical methods

Intervention groups

1

Description
Intervention group 1: Combined training + placebo (simultaneous intervention of combined training, which includes 20 minutes of aerobic training and 45 minutes of resistance training, 3-4 sessions per week, and exercises for 8 weeks from low to high intensity and in accordance with the principle of overload. We will take placebo pills).
Category
Treatment - Other

2

Description
Intervention group 2: Supplement group (3 tablets of 300 mg of bee propolis daily one hour after each meal with a glass of water and no exercise is done during the intervention period).
Category
Treatment - Other

3

Description
Intervention group 3: Combined exercise + supplement group (in this group, we will have simultaneous intervention exercise + propolis supplement, similar to the same protocol described in the previous section.
Category
Treatment - Other

4

Description
Control group 1: placebo group (this group of patients receive 3 tablets of the same shape, color and size of placebo daily and with the same protocol of the intervention group).

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital, Shiraz

Full name of responsible person
Dr. Sargolzaei Moghaddam

Street address
Saadi Gate Crossroads, Vali Asr Square

City
Shiraz

Province
Fars

Postal code
7136816695

Phone
+98 71 3223 1499

Email
beheshti_shiraz.hos@tamin.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University of Khorasgan Branch

Full name of responsible person
Dr. Farzaneh Taghian

Street address
University Boulevard, Arghavanieh, East J. Street

City
Khorasgan

Province
Isfehan

Postal code
۸۱۵۵۱-۳۹۹۹۸

Phone
+98 31 3535 4001

Email
info@khuisf.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Islamic Azad University of Khorasgan Branch

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University of Khorasgan Branch

Full name of responsible person
Fatemeh moayedi

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Sport physiology

Street address
No. 88, 25 meters from Shahid Sheikhi, South Hemmat, Moallem Square

City
Shiraz

Province
Fars

Postal code
۷۱۸۵۹۹۹۱۱۵

Phone
+98 71 3632 2954

Email
Fatemeh_m8040@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University of Khorasgan Branch

Full name of responsible person
Fatemeh moayedi

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Sport physiology

Street address
No. 88, 25 meters from Shahid Sheikhi, South Hemmat, Moallem Square

City
Shiraz

Province
Fars

Postal code
۷۱۸۵۹۹۹۱۱۵

Phone
+98 71 3632 2954

Email
Fatemeh_m8040@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University of Khorasgan Branch

Full name of responsible person
Fatemeh moayedi

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Sport physiology

Street address
No. 88, 25 meters from Shahid Sheikhi, South Hemmat, Moallem Square

City
Shiraz

Province
Fars

Postal code
۷۱۸۵۹۹۹۱۱۵

Phone
+98 71 3632 2954

Email
Fatemeh_m8040@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available

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

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

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals.

When the data will become available and for how long
The start of the data access period is 6 months after the publication of the articles.

To whom data/document is available
The data will only be available to researchers working at academic institutions.

Under which criteria data/document could be used
The data will be generally available and unpublishable by the recipient.

From where data/document is obtainable
To receive research information, send an email to fatemeh_m8040@yahoo.com

What processes are involved for a request to access data/document
After obtaining permission from the project manager, the data will be sent.

Comments