Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 (IL6) 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 levels of adipolin and inflammatory factor and glycemic index 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. Patients are entered into intervention or placebo groups based on a table of random numbers.

Settings and conduct
The statistical population of this study is women with type 2 diabetes in Shiraz. 40 people from this group are selected based on the inclusion and exit criteria of the research and are randomly divided into 4 groups by blindness. Blood sampling is done from the beginning of training sessions and 48 hours after the end of training. Research variables will be measured after 8 weeks of intervention. The results are analyzed using appropriate statistical methods.

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 honey, 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: **IRCT20211229053561N2**
Registration date: **2022-01-29, 1400/11/09**
Registration timing: **prospective**

Last update: **2022-01-29, 1400/11/09**
Update count: **0**

Registration date
2022-01-29, 1400/11/09

Registrant information

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Fatemeh Moayedi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-04, 1400/11/15
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 (IL6) 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:
Confirmation of type 2 diabetes (fasting blood sugar greater than 126 mg / dL, oral glucose tolerance test equal to or greater than 200 mg / dL, glycosylated hemoglobin 5.6% 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
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, subjects are randomly selected according to the law of random allocation. In this way, after determining the sample size, people will be equally divided into four groups (combined exercise + supplement, combined exercise + placebo, placebo, supplement).

Blinding (investigator's opinion)
Double blinded
Blinding description
Patients in the supplement and exercise + supplement group take 3 tablets with a dose of 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. Since the placebo and propolis supplement are placed inside the capsule in exactly the same way, participants and researchers are not aware of the type of supplement they receive.
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
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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
Non-insulin-dependent 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: The first intervention group, 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 training for 8 weeks from low to high intensity and following the principle of extra Once done, 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: 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: 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

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Sponsors / Funding sources

1

Sponsor
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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
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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