

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

Name

Fatemeh Moayed

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

2022-02-04, 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

City

Khorasgan

Province

Isfahan

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

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

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

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

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

Isfahan

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 moayed

Position

PhD student

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad University of Khorasgan Branch

Full name of responsible person

Fatemeh moayed

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 moayed

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