Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of propolis tablet on glycemic control, lipid profile and insulin resistance in comparison with placebo in patients with type 2 diabetes mellitus

Protocol summary

Summary

In this double-blind placebo controlled clinical trial, 67 volunteers (with considering 10% loss) who have diabetes type 2 will participate by random. Participants will be divided into 2 groups, intervention and control. we will request from the intervention group to use three tablets of propolis and the control group to use three tablets of placebo daily. Before and after the intervention, biochemical tests such as LDL, HDL, TG, Total Chol, FBS, HbA1c and Insulin will be measured. The height, weight and 24-hour dietary recalls will be measured too. Participants will be asked not to change their physical activity, diet and life style during the intervention. we will follow them by phone calls or visits. The intervention duration will be 12 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080218659N1**
Registration date: **2015-09-07, 1394/06/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-07, 1394/06/16

Registrant information

Name

Nazli Samadi Bilehsavar

Name of organization / entity

Shahid Sadooghi University of Medical Sciences and Health

Country

Iran (Islamic Republic of)

Phone

+98 35362406915

Email address

nazlisamadi510@gmail.com

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University Medical Sciences and Health Services

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of propolis tablet on glycemic control, lipid profile and insulin resistance in comparison with placebo in patients with type 2 diabetes mellitus

Public title

Effect of propolis on diabetes mellitus

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with type 2 diabetes mellitus, diagnosed 5-10 years ago, under treatment with oral hypoglycemic agents. Exclusion criteria: pregnancy, lactation, insulin therapy, any other diseases such as autoimmune, intestinal, liver, thyroid and cardiovascular diseases, vitamin and mineral supplementation, history of dermal or digestive hypersensitivity to propolis, any severe respiratory disease (such as asthma, chronic

bronchitis), report of side effects of propolis tablets.

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **67**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

A double blind study. Patients and researcher are blind about intervention and placebo groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd Shahid Sadoghi University of Medical Sciences Ethics Committee

Street address

University of Medical Sciences and Health Services-Bahonar sq-YAZD

City

Yazd

Postal code

Approval date

2014-11-26, 1393/09/05

Ethics committee reference number

17/1/179454/پ

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

Fasting Blood Glucose

Timepoint

Before and after intervention

Method of measurement

Enzymatic method (mg/dl)

2

Description

Fasting insulin

Timepoint

Before and after intervention

Method of measurement

ELISA(mU/l)

3

Description

Triglyceride

Timepoint

Before and after intervention

Method of measurement

Enzymatic method (mg/dl)

4

Description

Total cholesterol

Timepoint

Before and after intervention

Method of measurement

Enzymatic method (mg/dl)

5

Description

LDL-C

Timepoint

before and after intervention

Method of measurement

Friedewald formula (mg/dl)

6

Description

HDL-C

Timepoint

before and after intervention

Method of measurement

Precipitation(mg/dl)

7

Description

Insulin resistance, sensitivity

Timepoint

Before and after intervention

Method of measurement

Software

Secondary outcomes

1

Description
HA1C
Timepoint
The baseline and three months after the intervention
Method of measurement
Turbidometry

Intervention groups

1

Description
Patients in intervention group receive propolis tabletes,3 times a day, for 12 weeks.Each tablet contains 300 mg propolis.
Category
Treatment - Drugs

2

Description
Patients in control group, receive placebo tablets 3 times a day for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Diabetes Research Center
Full name of responsible person
Masoud Rahmanian, Assistant Professor of Endocrinology
Street address
Diabetes Center, Honar Alley, Bahonar Sq
City
Yazd

2

Recruitment center
Name of recruitment center
Emam Ali Clinic
Full name of responsible person
Masoud Rahmanian, Assistant Professor of Endocrinology
Street address
Dolat Abad Crossroad
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Yazd Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Amirhooshang Mehrparvar
Street address
Vice Chancellor for Research,Yazd University of Medical Sciences,Bahonar.Sq,yazd
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Yazd Shahid Sadoughi University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Sadooghi University of Medical Sciences and Health
Full name of responsible person
Nazli Samadi Bilehsavar
Position
MSc student of Health Sciences in Nutrition
Other areas of specialty/work
Street address
Department of Health, Imam Reza building, Student Blvd, Imam Hossein Square
City
Yazd
Postal code
89165887
Phone
+98 35 3624 0691
Fax
+98 36238555
Email
nazlisamadi510@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Sadooghi University of Medical Sciences and Health Services in Yazd

Full name of responsible person
Hassan Mozaffari Khosravi

Position
PhD of Nutrition

Other areas of specialty/work

Street address
Department of Health, Imam Reza building, Student Blvd, Imam Hossein Square

City
Yazd

Postal code
89165887

Phone
+98 35 3624 0691

Fax

Email
mozaffari.kh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Sadooghi University of Medical Sciences and Health

Full name of responsible person
Nazli Samadi Bilehsavar

Position
MSc student of Health Sciences in Nutrition

Other areas of specialty/work

Street address
Department of Health, Imam Reza Building, Student Blvd, Imam Hossein Square

City
Yazd

Postal code
89165887

Phone
+98 35362406915

Fax

Email
nazlisamadi510@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty