Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 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

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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
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Position
MSc student of Health Sciences in Nutrition
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Person responsible for scientific inquiries

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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