

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of propolis on glycemic control, Lipid profile, renal function and inflammatory biomarkers in patients with type 2 diabetes mellitus: A randomized double blind clinical Trial.

Protocol summary

Summary

The purpose of this study is to evaluate the effect of propolis on glycemic control, Lipid profile, renal function and inflammatory biomarkers in patients with type 2 diabetes. In this placebo controlled double blind clinical trial study, 100 volunteer patients with diabetes mellitus that has Hemoglobin A1c (HbA1c) Test between 5.9-8% and Fast blood sugar between 126-200 mg/dl which only use oral hypoglycemic agents and were diagnosed less than 10 years will be randomly selected and divided to control and treatment groups. Patients in treatment group take 2 capsules of propolis daily whereas in control group 2 placebo capsules will given to patients. Level of fast blood sugare, 2 hours postprandial glucose, hemoglobine A1C , high density lipoprotein, low density lipoprotein, Total cholesterol, triglyceride, serum Insulin, blood urea nitrogen, creatinine, uric acid, alkanin phosphatase and liver enzymes, inflammation factors like TNFa, IL10, IL6, hs-CRP and also height and weight will be evaluated in the beginning and in the end of study. Patients will be asked not changing their physical exercises, diet and life style duration of study which take 90 days. In the end effect of propolis on measured factors will be statistically evaluated and reported.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092730008N1**
Registration date: **2017-09-07, 1396/06/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-07, 1396/06/16

Registrant information

Name

Maryam Jenabi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3161

Email address

jenabi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapour of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of propolis on glycemic control, Lipid profile, renal function and inflammatory biomarkers in patients with type 2 diabetes mellitus: A randomized double blind clinical Trial.

Public title

The effect of propolis in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 25-80 years; Hemoglobin A1c

(HbA1c) Test between 5.9-8%; Fast blood sugar between 126-200 mg/dl; patients were diagnosed less than 10 years; patients should only use oral hypoglycemic agents
Exclusion criteria: Pregnancy and lactation; Insulin dependent diabetes; sensitivity to honey or bee products; Severe renal or hepatitis failure

Age

From **25 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapour University of Medical Sciences

Street address

Golestan

City

Ahvaz

Postal code

Approval date

2017-07-29, 1396/05/07

Ethics committee reference number

IR.AJUMS.REC.1396.430

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.9

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Serum

Timepoint

in the beginning, monthly and in the End of Intervention

Method of measurement

mg/dl with using specific serum kit

2

Description

Body Mass Index (BMI)

Timepoint

in the beginning and in the End of Intervention

Method of measurement

kg/m2 by measuring height and weight and use of scale

3

Description

Blood pressure

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mmHg by using indicator

4

Description

2 hours post prandial glucose

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

5

Description

HbA1C

Timepoint

in the beginning and in the End of Intervention

Method of measurement

% by using specific serum kit

6

Description

Triglyceride

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

7

Description

cholesterol

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

8

Description

High Density Lipoprotein (HDL)

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

9

Description

Low Density Lipoprotein (LDL)

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

10

Description

Very Low Density Lipoprotein (VLDL)

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

11

Description

ALANIN AMINOTRANSFERASE

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

12

Description

ASPARTATE AMINOTRANSFERASE

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

13

Description

ALKALIN PHOSPHATASE

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

14

Description

BLOOD UREA NITROGEN

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

15

Description

Creatinine

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

16

Description

URIC ACID

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/dl by using specific serum kit

17

Description

Serum Insulin

Timepoint

in the beginning and in the End of Intervention

Method of measurement

IU/ml by using specific serum kit

18

Description

IL6

Timepoint

in the beginning and in the End of Intervention

Method of measurement

Pg/ml by using specific serum kit

19

Description

IL1-B

Timepoint

in the beginning and in the End of Intervention

Method of measurement

Pg/ml by using specific serum kit

20

Description

Tumor Necrosis Factor a

Timepoint

in the beginning and in the End of Intervention

Method of measurement

Pg/ml by using specific serum kit

21

Description

High sensitivity C- reactive protein

Timepoint

in the beginning and in the End of Intervention

Method of measurement

ng/ml by using specific serum kit

22

Description

Estimated Glomerular Filtration Rate

Timepoint

in the beginning and in the End of Intervention

Method of measurement

mg/min/1.73m² by using formula

23

Description

Homeostasis model assessment Insulin resistance

Timepoint

in the beginning and in the End of Intervention

Method of measurement

%by using formula

24

Description

Homeostasis model assessment of β -cell function

Timepoint

in the beginning and in the End of Intervention

Method of measurement

%by using formula

Secondary outcomes

1

Description

sensitivity

Timepoint

in the beginning, monthly and in the end of intervention

Method of measurement

patient complain, physical examination

Intervention groups

1

Description

Propolis, capsule 500mg, oral, twice daily, 3 month

Category

Treatment - Drugs

2

Description

Soya, capsules 500mg, oral, twice daily, 3 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Treatment Center of Golestan Hospital

Full name of responsible person

Dr. Mehrnoosh Zakerkish, Endocrine Specialist

Street address

Golestan

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

DR. Narges Zaeemzadeh

Street address

Pharmacology Department, Diabetes center, Ahvaz
Jundishapour University of Medical Sciences

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundishapour 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

School of Pharmacy, Ahvaz Jundishapour University of
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Full name of responsible person

Maryam Jenabi

Position

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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