Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 purpuse 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, hemoglubine A1C , high density lipoprotein, low density lipoprotein, Total cholesterol, triglyceride, serum Insulin, blood urea nitrogen, creatinine, uric acid, alkalin 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
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Iran (Islamic Republic of)
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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; sensivity 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 Scinces

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
cholestrol

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
ASPATRTATE 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 sensitity 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 Glomelural Filtration Rate
Timepoint
in the beginning and in the End of Intervention
Method of measurement
mg/min/1.73m2 by using formula

23

Description
Homestasis 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
sensivity
Timepoint
in the begining, 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
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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

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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