

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Survey of oral propolis effect on antioxidant status, lipid peroxidation, lipid profiles, Insulin resistance, blood glucose and glycosylated hemoglobin in patients with type 2 diabetes: A double-blind placebo-controlled clinical trial

Protocol summary

Summary

The aim of this randomized, placebo-controlled trial is to investigate the effects of propolis supplementation on some blood biochemical parameters in people with type II diabetes. Sixty patients with type II diabetes are of both sexes to participate in the study. Eligible patients will randomly be divided into two groups using a table of random numbers. Participants in the intervention group received three capsules of 500 mg of propolis for two months and the control group received placebo. Fasting blood glucose, lipid profile, oxidized LDL, fructosamine, glycosylated hemoglobin, insulin, insulin resistance, antioxidant capacity, glutathione peroxidase, dismutase (SOD), Catalase, inflammatory markers TNF α and CRP, interleukin 6 and 17 and liver enzymes aspartate aminotransferase and alanine aminotransferase in two groups before the intervention and at the end of the study measured and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041019669N4**

Registration date: **2017-05-20, 1396/02/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3375 2135

Email address

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Recruitment status

Recruitment complete

Funding source

Research Qazvin University of Medical Science

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of oral propolis effect on antioxidant status, lipid peroxidation, lipid profiles, Insulin resistance, blood glucose and glycosylated hemoglobin in patients with type 2 diabetes: A double-blind placebo-controlled clinical trial

Public title

Survey of oral propolis effect in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having the type 2 diabetes -voluntary

consent for participation in the study Exclusion criteria: - use of multivitamin-mineral supplements at least 6month before the study -smoking, alcohol abuse -treatment with insulin -having the hepatic, renal failure, cardiovascular, celiac, gastrointestinal, rheumatic

Age
From **30 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study, the researcher and patient to the drug and placebo are blind, so this is a double-blind study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Postal code

Approval date

2017-02-27, 1395/12/09

Ethics committee reference number

IR.QUMS.REC.1395.294

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 Sugar

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA

2

Description

Insulin

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA

3

Description

HbA1c

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA

4

Description

Lipid profile

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA

5

Description

Added at 2017-10-28: Fructosamine

Timepoint

Added at 2017-10-28: Before intervention and 2 month after intervention

Method of measurement

Added at 2017-10-28: Eliza

Secondary outcomes

1

Description

Antioxidant indices

Timepoint

Before intervention and two months after intervention

Method of measurement

ELISA

2

Description

Added at 2017-10-28: Inflammatory factors

Timepoint

Added at 2017-10-28: Before intervention and 2 month after intervention

Method of measurement

Added at 2017-10-28: Eliza

Intervention groups

1

Description

Control group: placebo weight flour supplementation, 1.5 gr daily, three capsules for 2 months

Category

Placebo

2

Description

Intervention group: Propolis capsules, 1500 mg daily, three capsules of 500 mg, for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital of Qazvin University of Medical Sciences

Full name of responsible person

Dr. Hossein Khadem Haghighian

Street address

Velayat Hospital, Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

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, Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Hossein Khadem Haghighian

Position

Nutrition Ph.D

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Other areas of specialty/work

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Full name of responsible person

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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