Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effects of intake of Royal Jelly on serum glucose, Insulin, Hb A1c, Apo- AI, Apo- B levels, insulin resistance & blood pressure in type 2 diabetic patients refferred to Endocrine and Metabolism Institue of Iran University of Medical Sciences

Protocol summary

Summary

The objective of this study is to evaluate the effects of intake of Royal Jelly in type 2 diabetes. A total of 50 patients with type 2 diabetes, who referred to Endocrine and Metabolism Institue of Iran University of Medical Sciences, will be allocated to 2 groups by stratified randomization method. They will receive 3 capsules of royal jelly (1000 mg) daily for 8 weeks in the intervention group and placebo in the control group. Serum glucose, insulin, HbA1c, APO-A1, APO-B levels and Homa-R, blood pressure , 24-hour dietary recall, none consecutive 3-day 24-hour dietary recalls (including 2 usual days and one holiday) will be assessed and compared at the first week, at the end of 4th week, and at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905102709N8**
Registration date: **2010-12-01, 1389/09/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-01, 1389/09/10

Registrant information

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Farzad Shidfar
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2010-11-06, 1389/08/15

Expected recruitment end date

2011-01-06, 1389/10/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of intake of Royal Jelly on serum glucose, Insulin, Hb A1c, Apo- AI, Apo- B levels, insulin resistance & blood pressure in type 2 diabetic patients refferred to Endocrine and Metabolism Institue of Iran University of Medical Sciences

Public title

Effects of intake of royal jelly in type 2 diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: confirmed diabetes type 2 based on physicians diagnosis, being volunteer or willingness to attend, no history of cardiovascular, liver or kidney diseases, not receiving insulin prior to 3 months before the trial, age between 20-65 years old, HbA1c 6-8%, no

allergy to honey or its products, BMI between 20-30, duration of type 2 diabetes mellitus for 5 -10 years, no history of smoking and alcohol drinking Exclusion criteria: cholesterol >=240mg/dl, TG>=400mg/dl, incomplete consumption of royal jelly, creation of allergy during the study period, using of any kind of food supplements, pregnancy, lactation, using of oral contraceptive pills, changing medication dosage

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Iran University of Medical Sciences

Street address
next to Milad tower, Shahid Hemmat Highway

City
Tehran

Postal code

Approval date
2010-10-10, 1389/07/18

Ethics committee reference number
2402

Health conditions studied

1

Description of health condition studied
DIABETES MELLITUS

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
fast blood sugar

Timepoint
Before and after the intervention

Method of measurement
Enzymatic,Glucose oxidase

2

Description
serum Insulin Level

Timepoint
Before and after the intervention

Method of measurement
fast serum insulin level,IRMA method

3

Description
HOMA-R

Timepoint
Before and after the intervention

Method of measurement
HOMA-IR=Glucose x Insulin/405,Calculating

4

Description
HbA1c

Timepoint
Before and after the intervention

Method of measurement
fast HbA1c serum level,Chromatography

5

Description
APO-A1

Timepoint
Before and after the intervention

Method of measurement
fast APO-A1 serum level,Immunoturbidimetry

6

Description
APO-B

Timepoint
before and after intervention

Method of measurement
fast APO-B serum level,Immunoturbidimetry

7

Description
blood pressure

Timepoint
at the baseline, at the middle and the end of the study

Method of measurement

blood pressure,sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 3 royal jelly (1000mg) capsules daily
Category
Prevention

2

Description
Control group: placebo 3 (1000mg) capsules daily
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine and Metabolism Institute of Iran University of Medical Sciences
Full name of responsible person
Dr. Mojtaba Malek
Street address
Firoozgar Hospital, Behafarin street, Valiasr square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Farzad Shidfar
Street address
Next to Milad tower, Hemmat Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
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Web page address

Person responsible for updating data

Contact

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