Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Royal Jelly intake on serum total antioxidant capacity,malondialdehyde and interleukin-6 levels in type 2 diabetic patients

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 Tehran 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 total antioxidant capacity ,malondialdehyde,interleukin-6, 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: **IRCT201103012709N18**
Registration date: **2011-03-14, 1389/12/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-03-14, 1389/12/23

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-03-06, 1389/12/15

Expected recruitment end date

2011-06-05, 1390/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Royal Jelly intake on serum total antioxidant capacity,malondialdehyde and interleukin-6 levels in type 2 diabetic patients

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
Tehran University of Medical Sciences

Street address
next to Milad tower, Shahid Hemmat

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
total antioxidant capacity

Timepoint
Before and after the intervention

Method of measurement
plasma antioxidant activity ,FRAP method

2

Description
serum malondialdehyde

Timepoint
Before and after the intervention

Method of measurement
fast plasma malondialdehyde level,spectrophotometry

3

Description
interleukin-6

Timepoint
Before and after the intervention

Method of measurement
fast plasma interleukin-6,ELISA method

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 Tehran 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
Tehran 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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Farzad Shidfar
Position
professor /nutrition PhD
Other areas of specialty/work
Street address
Next to Milad tower, Hemmat Highway
City
Tehran
Postal code
Phone
+98 21 8860 2218
Fax
Email
farzadshidfar@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Farzad Shidfar
Position
Nutrition Phd
Other areas of specialty/work
Street address
Next to Milad tower,Hemmat Highway
City
Tehran
Postal code
Phone
+98 21 8860 2218
Fax
Email
farzadshidfar@yahoo.com
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