

# 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 referred to Endocrine and Metabolism Institute 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 Institute 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

###### 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

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 referred to Endocrine and Metabolism Institute 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  $\geq$ 240mg/dl, TG $\geq$ 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

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

Iran 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

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##### 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*