

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of single dose of royal jelly on serum glucose, insulin and C-peptide level in type 2 diabetic patients.

#### Protocol summary

##### Summary

This study aimed to investigate the effect of a single dose of royal jelly on serum glucose, insulin and c-peptide in type 2 diabetic patients. Forty patients with type 2 diabetes will be randomly divided in 2 groups including 20 patients in the intervention group and 20 patients in the control group. After explaining the study procedure for the patients and informed consent, in the morning after an 8-hour fasting blood sample will be taken. The intervention group will be received 10 g royal jelly, however the control group will be received 10 g paraffin. One and two hours after administration, blood samples will be obtained. Serum glucose, insulin and C-peptide in each sample will be measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201306049626N2**

Registration date: **2013-06-13, 1392/03/23**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-06-13, 1392/03/23

##### Registrant information

##### Name

Majid Mobaseri

##### Name of organization / entity

Tabriz university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7850

##### Email address

t.u.end.d@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Bone disease health center, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-06-22, 1392/04/01

##### Expected recruitment end date

2013-12-21, 1392/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of single dose of royal jelly on serum glucose, insulin and C-peptide level in type 2 diabetic patients.

##### Public title

Effect of royal jelly on serum glucose and insulin in type 2 diabetic patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: having type 2 diabetes; age 30-65 years old; treated with glucose-lowering drugs. Exclusion criteria: insulin therapy; history of allergy to honey or bee products; pregnancy; lactation; renal failure; a history of any type of metabolic disease other than type 2 diabetes such as proved thyroid disease.

##### Age

From **25 years** old to **65 years** old

##### Gender

Both

##### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 40

## 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

Tabriz University of Medical Sciences Ethics Committee

##### Street address

Faculty of Medicine- Daneshgah Ave. Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2013-05-13, 1392/02/23

#### Ethics committee reference number

9235

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes

#### ICD-10 code

E11

#### ICD-10 code description

Endocrine, nutritional and metabolic diseases

## Primary outcomes

### 1

#### Description

Plasma glucose levels

#### Timepoint

Before and one hour and two hour after intervention

#### Method of measurement

Paraclinical

### 2

#### Description

Plasma insulin levels

#### Timepoint

Before and one hour and two hour after intervention

#### Method of measurement

Paraclinical

### 3

#### Description

Plasma C-peptide levels

#### Timepoint

Before and one hour and two hour after intervention

#### Method of measurement

Paraclinical

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:10 g royal jelly in morning after an 8-hour fasting

#### Category

Treatment - Drugs

### 2

#### Description

Placebo group: 10 g placebo tablet (containing edible paraffin) jelly in morning after an 8-hour fasting

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital

##### Full name of responsible person

Dr. Majid Mobaseri

##### Street address

Imam Reza hospital- Tabriz

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research deputy of Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Shakuri Kazem

**Street address**Golgasht Street ,Tabriz University of Medical Sciences  
,central building II,third floor**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research deputy of Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Majid Mobaseri

**Position**

Associate profeseor- endocrinologist

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

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Tabriz University of Medical Sciences

**Full name of responsible person**

dr.Shahram Ghiyasvand

**Position**

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**Web page address****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*