Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of royal jelly supplementation on serum antioxidants status, lipid profiles, insulin resistance and glucose level and inflammatory factors in type 2 diabetes

Protocol summary

Summary
This randomized clinical trial is designed to determine the effect of royal jelly supplementation on serum antioxidants status, lipid profiles, insulin resistance, glucose level and inflammatory factor in type 2 diabetes. Fifty patients with type 2 diabetes will be randomly divided in 2 groups including 25 patients in intervention group (which will be receive royal jelly tablets) and 25 patients in control group. The intervention group will be received 1000 mg royal jelly tablets, however the control group will be received 1000 mg paraffin tablet every day for two months. The antioxidant indices, lipid profile and insulin resistance and fasting blood glucose will be measure before and after study. Also for assessment of food intake and appetite, 24 hours food recall and appetite questionnaire will be completed before and after study.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201011131197N5**
Registration date: **2011-02-28, 1389/12/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2011-02-28, 1389/12/09

Registrant information
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Recruitment status
Recruitment complete

Funding source
Nutritional Research Center Of Tabriz University Of Medical Sciences

Expected recruitment start date
2010-12-11, 1389/09/20
Expected recruitment end date
2011-02-09, 1389/11/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of royal jelly supplementation on serum antioxidants status, lipid profiles, insulin resistance and glucose level and inflammatory factors in type 2 diabetes

Public title
The effect of royal jelly supplementation on type2 diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age 30-65 years old, BMI 25 until 30, having diabetes at least 6 months prior to the study, consumption of blood glucose lowering drugs Exclusion criteria: consumption of antioxidants supplements during last 3 month prior to the study, using insulin, pregnancy,

lactation, acute renal disease, hypothyroidism, hyperthyroidism, allergy

Age
From **30 years** old to **65 years** old

Gender
Female

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
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Research Ethics Committee Of Tabriz University Of Medical Sciences

Street address
Tabriz University Of Medical Sciences, Attar Neyshabori Street, Tabriz, East Azerbayjan, Iran, Islamic Republic Of

City
Tabriz

Postal code

Approval date
2010-11-14, 1389/08/23

Ethics committee reference number
8939

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
serum antioxidant status

Timepoint
8weeks

Method of measurement
measurment of SOD,GPX-H,TAC,MDA

2

Description
lipid profiles

Timepoint
8 weeks

Method of measurement
TC, TG, LDL, HDL

3

Description
insulin level

Timepoint
8 weeks

Method of measurement
Serum level of insulin

4

Description
blood glucose

Timepoint
8 weeks

Method of measurement
fasting blood glucose

5

Description
Inflammatroy factors

Timepoint
8 weeks

Method of measurement
HS-CRP

Secondary outcomes

1

Description
Anthropomethric indices

Timepoint
8 Weeks

Method of measurement
Weight, Height, BMI

2

Description
appetite

Timepoint

8 weeks

Method of measurement

questionnaire

3

Description

dietary intake

Timepoint

8weeks

Method of measurement

24 hours-food recal questionnaire

Intervention groups

1

Description

intervention group: 1000 mg/day royal jelly tablet with breakfast for 8 weeks

Category

Treatment - Drugs

2

Description

Placebo group: 1000 mg/day placebo tablet (containing edible paraffin) with breakfast for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology Clinic Of Sina Hospital

Full name of responsible person

Dr. Mobasseri

Street address

Sina Hospital- Hafez Square- Azadi Street- Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutritional Research Center, Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Ostadrahimi

Street address

Block B, Third Floor, Health And Nutrition Faculty, Tabriz University Of Medical Sciences , Attar Neyshabori Street,Tabriz, East Azerbayjan,Iran, Islamic Republic Of

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nutritional Research Center, 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

Nutritional Research Center, Tabriz University Of Medical Sciences

Full name of responsible person

Dr Reza Mahdavi

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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