Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Effect of honey consumption on the lipid profile, blood pressure, and serum levels of adiponectin and C-reactive protein in patients with type 2 diabetes

Protocol summary

Summary

The purpose of this study is determination of the effect of honey consumption on glycemic control and oxidant and antioxidant compounds in patients with type 2 diabetes. The study is cross-sectional with two groups, the intervention group that will receive honey and a control group. The sample size is 50 in each group. Participants are patients with type 2 diabetes with fasting blood sugar < 200 mg/dl. Participants should be non-insulin dependent without a critical medical condition or infectious disease. Hospitalization or involvement in serious diseases will exclude patients from the study. The participants will be asked not to change their diet, life style, and physical activity during the study. In the first sequence of the study, one group will receive honey (50 g/day) for 8 weeks while the control group will be left without any intervention. Then a 4-week wash-out period will be established in which both of the groups do not consume honey. After the wash-out period, the second sequence of study will start and the role of groups will interchange. Both groups will be on weight-maintenance diet throughout the study. At the beginning and end of each sequence of study, blood samples will be collected to assess the changes (lipid profile, serum adiponectin and c-reactive protein).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062122364N2**
Registration date: **2015-08-04, 1394/05/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-04, 1394/05/13

Registrant information

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Fateme Sadeghi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-14, 1394/01/25

Expected recruitment end date

2015-09-16, 1394/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of honey consumption on the lipid profile, blood pressure, and serum levels of adiponectin and C-reactive protein in patients with type 2 diabetes

Public title

Effect of honey on type 2 diabetes

Purpose

Other

Inclusion/Exclusion criteria
Inclusion criteria: type II diabetic patient with a fasting blood sugar less than 200 milligrams per deciliter; free of a history or presence of malignancy; acute and emergency states; a history of major operations; a drug history of Immunomodulators, cytotoxic or immunosuppressive agents; no pregnancy or lactation if female; and not using insulin for diabetes control.
Exclusion criteria: Participants will exclude in the case of any kind of acute diseases; hospitalization or meet the criteria mentioned in Inclusion criteria.

Age
From **35 years** old to **75 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)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Siraz University of Medical Sciences

Street address
Central Building of Shiraz University of Medical Sciences, Zand Ave

City
Shiraz

Postal code
7134814336

Approval date
2015-03-08, 1393/12/17

Ethics committee reference number
CT-P-9386-8456

Health conditions studied

1

Description of health condition studied
diabetes

ICD-10 code
E10, E11,

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

Primary outcomes

1

Description
adiponectin

Timepoint
Baseline, 8 weeks after baseline, the end of the washout period, 8 weeks after the start of the second period

Method of measurement
ELISA

2

Description
C-reactive protein

Timepoint
Baseline, 8 weeks after baseline, the end of the washout period, 8 weeks after the start of the second period

Method of measurement
ELISA

Secondary outcomes

1

Description
Total cholestrol

Timepoint
Baseline, 8 weeks after baseline, the end of the washout period , 8 weeks after the start of the second period of study

Method of measurement
Pars Azmun Kit

2

Description
triglyceride

Timepoint
Baseline, 8 weeks after baseline, the end of the washout period , 8 weeks after the start of the second period of study

Method of measurement
Pars Azmun Kit

3

Description
LDL cholestrol

Timepoint
Baseline, 8 weeks after baseline, the end of the washout period , 8 weeks after the start of the second period of study

Method of measurement
Pars Azmun Kit

4

Description
HDL cholestrol
Timepoint
Baseline, 8 weeks after baseline, the end of the washout period , 8 weeks after the start of the second period of study
Method of measurement
Pars Azmun Kit

5

Description
blood pressure
Timepoint
Baseline, 4 weeks after baseline, 8 weeks after baseline, the end of the washout period, 4 weeks after the start of the second period of study , 8 weeks after the start of the second period of study
Method of measurement
mercury manometer

Intervention groups

1

Description
The intervention group consume Astragalus honey (50 grams per day) three times between meals for 8 weeks.After wash out period(4 weeks) , they will not consume honey(8 weeks.)
Category
Other

2

Description
Control group do not consume honey.After wash out period, they will consume honey for 8 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmad Nader Kazemi clinic
Full name of responsible person
Dr. Mohamad Marzughi
Street address
Valiasr square, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shiraz University of Medical Science
Full name of responsible person
Dr Seyed Basir Hashemi
Street address
Central Building of Shiraz University of Medical Science , Zand Ave
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Shiraz University of Medical Science
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
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Full name of responsible person
Dr Masoume Akhlaghi
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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