Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of honey consumption in comparison with not taking honey on glycemic control and oxidant and antioxidant compounds 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 a cross-over trial 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 (fasting blood sugar, insulin levels، serum malondialdehyde, and total antioxidant capacity).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052222364N1**
Registration date: **2015-07-26, 1394/05/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-26, 1394/05/04

Registrant information

Name

Fateme Sadeghi

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Science

Expected recruitment start date

2015-04-09, 1394/01/20

Expected recruitment end date

2015-09-11, 1394/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of honey consumption in comparison with not taking honey on glycemic control and oxidant and antioxidant compounds in patients with type 2 diabetes

Public title

Effect of honey consumption 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, free of 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

Random allocation to intervention or control groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Science

Street address

Central Building of Shiraz University of Medical Science , Zand Ave

City

Shiraz

Postal code

Approval date

2015-03-16, 1393/12/25

Ethics committee reference number

CT-9374-7434

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

fasting blood sugar

Timepoint

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

Method of measurement

Pars Azmun Kit

2

Description

Insulin level

Timepoint

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

Method of measurement

Immunoradiometric Assay

3

Description

serum malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry method

4

Description

Serum total antioxidant capacity

Timepoint

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

Method of measurement

Ferric reducing ability of plasma method (FRAP method)

Secondary outcomes

1

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

2

Description
weight
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 stud
Method of measurement
digital scale

3

Description
waist circumference
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
meter

4

Description
hip circumference
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
meter

Intervention groups

1

Description
The intervention group consume Astragalus honey (50 grams per day) three times between meals for 8 weeks.
Category
Treatment - Other

2

Description
Control group do not consume honey.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmad Nader kazemi clinic
Full name of responsible person
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, Shiraz
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
Shiraz University of Medical Science
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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