Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of the effect of probiotic honey supplementation compared with the control honey on metabolic profiles in patients with diabetic nephropathy

Protocol summary

Study aim
Objective: The aim of this study is to determine the effects of probiotic honey supplementation on metabolic profiles including insulin resistance and lipid profiles in patients with diabetic nephropathy.

Design
Randomized, double-blind, placebo-controlled clinical trial, phase 3, 60 patients

Settings and conduct
60 patients with diabetic nephropathy of eligible and referred to Akhavan Clinic, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Patients with diabetic nephropathy with a proteinuria level>0.3 g/24 h, with or without elevation of serum creatinine levels and aged 45 to 85 years will be included in this study. Exclusion criteria: History of active infection within 3 months, the intake of probiotic and/or synbiotic supplements within 3 months and malignancy and/or liver cirrhosis.

Intervention groups
Intervention: Patients will be assigned to receive either probiotic honey (n=30) or control honey (n=30). Probiotic and control honey are similar in shape and size.

Main outcome variables
Outcomes: Insulin metabolism parameters (primary outcomes) and lipid profiles (secondry outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201705035623N115**
Registration date: **2017-05-29, 1396/03/08**
Registration timing: **retrospective**
Last update: **2019-09-22, 1398/06/31**
Update count: **1**

Registration date
2017-05-29, 1396/03/08

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 36 1534 3570

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asemi_z@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2017-05-20, 1396/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of probiotic honey supplementation compared with the control honey on metabolic profiles in patients with diabetic nephropathy

Public title

Effect of supplementation in treatment of patients with diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic nephropathy Aged 40 to 80 years Proteinuria level>0.3 g/24 h, with or without elevation of serum creatinine levels

Exclusion criteria:

History of active infection within 3 months The intake of probiotic and/or synbiotic supplements within 3 months Malignancy and/or liver cirrhosis

Age

From **45 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, after balanced blocked randomisation, all participants will have allocated into two treatment groups to take either probiotic honey or normal honey. Randomization will be done by the use of Stat Trek software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Akhavan Clinic in Kashan who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

81151-87159

Approval date

2017-03-07, 1395/12/17

Ethics committee reference number

IR.KAUMS.REC.1395.152

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

N08.3

ICD-10 code description

Glomerular disorders in diabetes mellitus (E10-E14 with common fourth character .2+)

Primary outcomes

1

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Total antioxidant

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

4

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
FPG
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
LDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Control group: 25 g control honey (Sekkeh Gaz, Isfahan, Iran), once a day, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Intervention group: 25 g probiotic honey (Sekkeh Gaz, Isfahan, Iran), 108 Lactobacillus sporogenes CFU/g, once a day, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhavan Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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Ghotbe Ravandi Boulevard, Kashan
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hamidi-gh@kaums.ac.ir
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, Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available